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UPM UNIVERSITI PUTRA MALAYSIA
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- Common Advanced Statistics in Medical & Health Science
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  OPEN FOR REGISTRATION
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  ii. 7th World Conference on Research Integrity. Cape Town, South Africa
  iii. 9th International Congress on Peer Review and Scientific Publication, Chicago IL
- International Statistical Institute: Objectives & Events

FROM THE EDITOR'S DESK

Check out the 9 Faculty Research Groups (FRG), 2 University Research Groups (URG) and 1 Research Centre of Excellence (RCOE) registered with the Faculty of Medicine and Health Sciences, UPM. Some of these are led by academic clinicians from HPUPM, and there are members from external organisations too. RECRUS Res. Newsl. will invite each of this group to introduce about the group's vision, mission, and scope of research, and how they plan to strive ahead to achieve their goals.

This issue highlights the definition of **predatory journals**, and how to recognise them. It comes from an informative website. Do delve in to learn more about it. Another interesting article is on the **clinical registers** that are currently available. URL links are provided and it will sure be one of the most useful article to keep and to return to for every clinical researchers and trialists.

The appraisals from the **Meta-Journal Hour (MJH) Series 7** on the *Malaysian Ivermectin I-TECH randomised controlled trial* is now available in both writing and video recording. The same is for the other previous MJH series. Look out for **MJH 9** when we will assess the effectiveness, feasibility, and limitation of a mobile stroke unit on neurological outcomes. It is potentially cost- and life-saving, and may have a huge impact in many of our cities where traffic is heavy and stroke unit like the Regional Emergency Stroke Quick (RESQ) Response Unit HPUPM is not within reach within the acceptable 4.5 hours.

Current Evidence section shares about the study on **Completeness of clinical evidence citation in trial protocols**. It serves as another reminder to conduct a proper literature review and registers search to better inform the new study so that the research question and study designs take into consideration of a better evidence gap to bridge, challenges to overcome with a more meticulous plans or methods. Unless these were done, the new study runs the risk of repeating unnecessary studies and wasting the valuable resources.

Do check out research related webinars and workshops by CRU, and international conferences in the coming months. Check out **International Statistical Institute (ISI)** and its planned activities. Do register for the online **International Clinical Trials Day** on 19th May where you will get to learn about the fundamentals of clinical trials including the Phase I trials, the common challenges and ethical aspects from national experienced clinicians. Also, register for webinars on the **Common Advanced Statistics in Medical & Health Science** and **Statistical tests Assumptions** that will clarify all the critical points from what they are and how to topics. They are for those with some knowledge in statistics, and wanted to solidify understanding on those areas of the statistics. Lastly, do consider to participate in the **Research Development Workshop** 25-26 August + 3-month if you want to get a strong foothold on clinical epidemiology and research methodology where the whole research process will be clearly delineated leaving you no qualms whatsoever about planning and conducting high-quality clinical research. It caters for 10 participants only who are committed to produce the outputs, and you may register as attendees otherwise. It is planned as hybrid sessions. Feel free to call CRU to clarify any query.

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BIL.	NAMA KUMPULAN	KETUA KUMPULAN	AHLI
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Source: Mr. Mohamad Taufik Rahmat, Assistant Registrar at the Deputy Dean's Office (Research and Internationalization).
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Supplementary references:

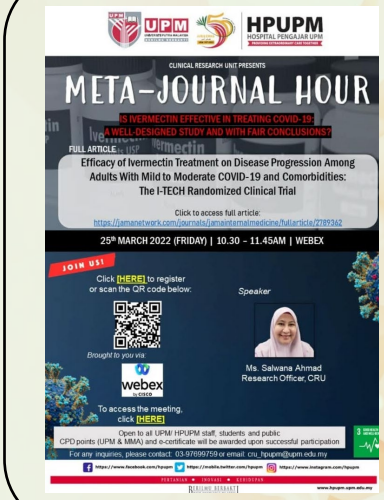
1. **Faculty research group initiatives**
2. **PELAN STRATEGIK PENYELIDIKAN (PERUBATAN DAN SAINS KESIHATAN) 2021 – 2025**
3. **Faculty's Research Strategic Plan**

APPRAISALS IN META-JOURNAL HOUR 7

By: Salwana Ahmad and BH Chew

The paper:

Efficacy of Ivermectin Treatment on Disease Progression Among Adults with Mild to Moderate COVID-19 and Comorbidities - The I-TECH Randomized Clinical Trial
doi:10.1001/jamainternmed.2022.0189



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Why was this study conducted?

Ivermectin, an inexpensive antiparasitic drug, is widely prescribed orally for COVID-19, contrary to the World Health Organization (WHO) recommendation to restrict the use of the drug in clinical trials (1). An in vitro study demonstrated the inhibitory effects of ivermectin against SARS-CoV-2(2). Some preliminary clinical studies suggest that ivermectin could be effective in the treatment and prevention of COVID-19 (3,4). In contrast, 2 randomized clinical trials from Colombia (4) and Argentina (6) found no significant effect of ivermectin on symptom resolution and hospitalization rates for patients with COVID-19. A Cochrane meta-analysis (7) also found insufficient evidence to support the use of ivermectin for the treatment or prevention of COVID-19. Accordingly, there was a need for better evidence to recommend either for or against the use of ivermectin. Thus, The Ivermectin Treatment Efficacy in COVID-19 High-Risk Patients (I-TECH) study was conducted to determine the efficacy of ivermectin in preventing progression to severe disease among high-risk patients with COVID-19 in Malaysia.

How was it done?

Trial designs and Patients

The Ivermectin Treatment Efficacy in COVID-19 High-Risk Patients (I-TECH) study was an open-label randomized clinical trial (RCT) conducted at 20 public hospitals and a COVID-19 quarantine center in Malaysia between May 31 and October 25, 2021. Within 7 days of patients' symptom onset, the study enrolled patients 50 years and older with laboratory-confirmed COVID-19, at least with 1 comorbidity, and mild to moderate clinical severity (stage 2-3 disease).

Primary and Secondary Outcomes

Primary Outcome Measure:

i. Number of patients who progressed to severe disease (hypoxic stage requiring supplemental oxygen to maintain oxygen saturation (SpO_2 95% or greater clinical stage 4 or 5).

Secondary Outcome Measure:

i. Time to progression to severe disease after enrollment.
ii. Number of patients who died in hospital within 28 days of study enrollment (28-day in-hospital all-cause mortality).
iii. Number of patients with complete resolution of symptoms by day 5 of enrollment.
iv. Changes in chest X-ray and laboratory investigations by day 5 of enrollment.
v. Number of patients admitted to ICU.
vi. Number of patients who required mechanical ventilation.
vii. Length of hospital stay in calendar days.

***Adverse events (AEs) and serious AEs (SAEs)** were evaluated and graded according to Common Terminology Criteria for Adverse Events (CTCAE), version 5.0 (8). The CTCAE terms are grouped by Medical Dictionary for Regulatory Activities (MedDRA) as Primary System Organ Class (SOC), the highest level of the MedDRA hierarchy. It is identified by the anatomical or physiological system, etiology, or purpose. Within each SOC, AEs are listed and accompanied by a description of severity (Grade). The CTCAE displays Grades 1 through 5 with unique clinical descriptions of the severity of each AE based on the general guidelines for reporting as such:

- Grade 1 Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
- Grade 2 Moderate; minimal, local, or non-invasive intervention indicated; limiting age-appropriate Instrumental Activities of Daily Living (preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.).
- Grade 3 Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care Activities of Daily Living (bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.).
- Grade 4 Life-threatening consequences; urgent intervention indicated. Grade 5 Death related to AE.

*All outcomes were captured from randomization until discharge from study sites or day 28 of enrollment, whichever was earlier.

Eligibility

Inclusion and exclusion criteria

Patients are eligible to be included in the study only if they fulfil ALL the following criteria:

1. RT-PCR or antigen test **confirmed COVID-19** cases
2. Aged **50 years and above**, with at least **one co-morbidity***
3. Within the first **7 days of illness (from symptom onset)**
4. Mild to moderate clinical severity (or stage 2 to 3 disease)

***Co-morbidities:**
Diabetes mellitus, hypertension, chronic kidney disease, chronic cardiac disease, chronic pulmonary disease, chronic liver disease, cerebral vascular disease, chronic neurological disorder, obesity (BMI ≥30kg/m2), dyslipidaemia, autoimmune disease, HIV, thyroid disease, malignancy, immunosuppressive therapy, and active smoker.

High-Risk patients were defined as those aged 50 years or older with comorbidity. Patients were staged according to clinical severity at presentation and disease progression following Disease Staging from COVID-19 Management Guideline in Malaysia (9) in **Table 1** below. Stages 2 and 3 were classified as a mild and moderate diseases (WHO clinical progression scale 2-4) (10), while stages 4 and 5 were classified as severe diseases (WHO clinical progression scale 5-9) (10).

Table 1. Clinical Severity in relation to Disease Staging from COVID-19 Management Guideline in Malaysia.

Clinical Severity	Disease Staging	Description
Asymptomatic	1	Asymptomatic
Mild	2	Symptomatic, No pneumonia
Moderate	3	Symptomatic, Pneumonia
Severe	4	Symptomatic, Pneumonia, Requiring supplemental oxygen
Severe	5	Critically ill

Exclusion Criteria

1) Asymptomatic stage 1 patient.
2) Patients with SpO_2 less than 95% at rest. (Unless it is an expected baseline SpO_2 due to pre-existing disease, e.g. COAD or pulmonary fibrosis).
3) Patients who need oxygen supplements.
4) Patients with concomitant bacterial, fungal, parasitic, or other viral infections before enrolment.
5) Patients with severe hepatic impairment (>Grade 3: ALT >10 times of upper normal limit).
6) Malabsorption syndrome or other clinically significant gastrointestinal diseases that may affect the absorption of the study drug (non-correctable vomiting, diarrhoea, ulcerative colitis, and others).
7) Pregnant or nursing women.
8) Female patients of reproductive age who cannot consent to contraceptive use of oral contraceptives, mechanical contraceptives such as intrauterine devices or barrier devices (pessaries, condoms), or a combination of these devices from the start of ivermectin administration to 7 days after the end of ivermectin administration.
9) Male patient who has a female partner of reproductive age and he cannot agree to use contraception from the start of ivermectin treatment till 7 days after treatment.
10) Patients receiving chemotherapy.
11) Patients who received interferon or drugs with reported antiviral activity against COVID-19 (favipiravir, hydroxychloroquine sulphate, chloroquine phosphate, lopinavir-ritonavir combination, remdesivir) in the past 7 days before enrolment.
12) Patients in whom this episode of infection is a recurrence or reinfection of COVID19.
13) Patients who have previously received ivermectin.

14) Patient receiving warfarin, or any medications known to interact with ivermectin.
15) Acute medical or surgical emergency (e.g., DKA/MI/stroke).
16) Other patients are judged ineligible by the principal investigator or sub-investigator.

Intervention and Control arm

- **Treatment group**: Ivermectin 0.4mg/kg/day for 5 days + standard-of-care
- **Control group**: Standard-of-care only.

- The ivermectin dosage for each patient in the intervention arm was calculated to the nearest 6-mg or 12-mg whole tablets. Details can be found in **Supplement 1** in the Supplemental Content of the paper.
- The standard of care for patients with mild to moderate disease consisted of symptomatic therapy and monitoring for signs of early deterioration based on clinical findings, laboratory test results, and chest imaging.

Study Schedules and Procedures

Timing of implementation / Item	Study period (Day 1 to maximum Day 28 of enrolment in hospital)			
	Day 1 (Enrollment before treatment initiation) (CRF 1)	Day 5 (Follow-up) (CRF 2)	Day of discharge* or in-hospital death (CRF 3)	Day of study event (clinical deterioration) (CRF 4)
Informed consent	●			
Patient characteristics ▪ *Patient's clinical history* ▪ *Anthropometric measurements*	●			
Clinical findings	● (a)	● (c)	●	● (c)
Clinical laboratory tests ▪ *CRP, full blood count, kidney and liver profiles, C-reactive protein levels*	● (a)	● (c)		● (c)
Chest X-Ray ▪ *Chest radiography*	●	●		●
Urine pregnancy test (b)	o			
Hospitalization	Mandatory hospitalization for at least the first 5 days of trial enrolment		(d)	
The adverse event assessment period	●	●	●	●

● : Required o : To be performed if necessary

a) Baseline blood tests are acceptable if done within 48 hours before enrolment. A baseline chest x-ray is acceptable if done within 48 hours before and 24 hours after enrolment.
b) A urine pregnancy test is needed for a female who is potentially pregnant.
c) Acceptable if done within 24 hours before and after.
d) Follow discharge criteria based on current national COVID-19 guidelines 17
*Discharge from the hospital or from the study at Day 28 (if still need to be in the hospital)

Screening, Enrolment and Randomization

Randomization was done based on a 1:1 ratio to either the intervention group receiving oral ivermectin (0.4 mg/kg body weight daily for 5 days) plus standard of care or the control group receiving the standard of care alone**.** The randomization was based on an investigator-blinded randomization list uploaded to REDCap, which allocated the patients via a central, computer-generated randomization scheme across all study sites during enrolment. The randomization list was generated independently using random permuted block sizes 2 to 6. The randomization was not stratified by site. Figure 1 shows the screening, enrolment and randomization allocation followed the Consolidated Standards of Reporting Trials (CONSORT) reporting guidelines.

The last patient follow-up was completed on October 25, 2021. After randomization, 4 patients were excluded; One patient in the control arm was diagnosed with dengue coinfection; in the intervention arm, 2 failed to meet inclusion criteria owing to symptom duration greater than 7 days and negative COVID-19

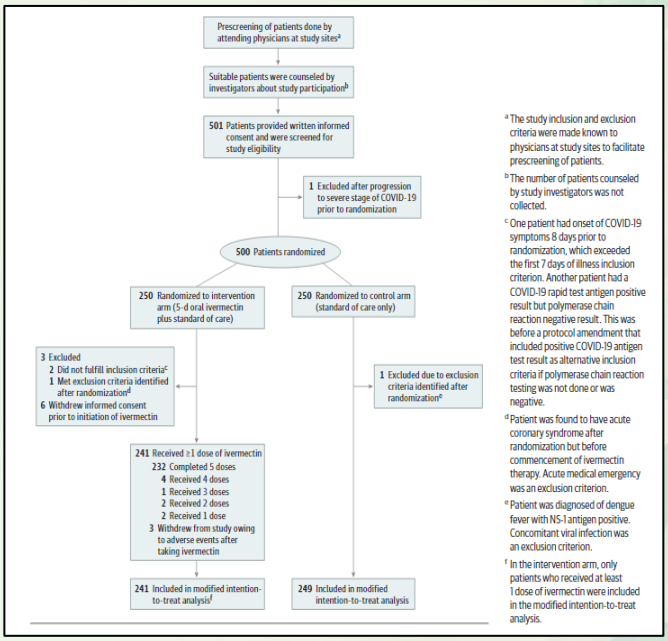

Figure 1. Screening, enrolment, randomization, and treatment assignment

RT-PCR test result, while 1 had acute coronary syndrome before ivermectin initiation. Before the initiation of intervention, 6 patients in the intervention arm withdrew consent.

The modified intention-to-treat population for the primary analysis included 490 patients (98% of those enrolled), with 241 in the intervention group and 249 in the control group (Figure 1).

Sample size calculation

Using two proportion formula (Pocock's formula)

$$n = [(p_1 (1-p_1) + p_2 (1-p_2)] \times (Z_\alpha + Z_\beta)^2 / (p_1-p_2)^2$$

$$n = \frac{[0.175(1-0.175) + 0.087(1-0.087)] \times (0.84+0.05)^2}{(0.175-0.087)^2}$$

= 228 per arm

Where:

n = required sample size
α = level of statistical significance
1-β = power of study
$z\alpha$ = value of the standard normal distribution cutting off probability α in one tail for a one – sided alternative or α/2 in each tail for a two sided alternative
$z\beta$ = value of the standard normal distribution cutting off probability β

- Expected 17.5% progression to severe disease in control group
- Clinically important result: reduce by 50% (8.75%)
- To:
  - Correctly identify true effect of Ivermectin with 80% probability.
  - - Avoid false inferring an effect when there is really none with 95% probability ($p<0.05$)

A minimum of **456** subjects was needed for the study. Considering potential dropouts, a total of 500 patients (250 patients for each group) were recruited.

Data analysis

Primary analyses were performed based on the modified intention-to-treat principle, whereby randomized patients in the intervention group who received at least 1 ivermectin dose and all patients in the control group would be evaluated for efficacy and safety. In addition, sensitivity analyses were performed on all eligible randomized patients, including those in the intervention group who did not receive ivermectin (intention-to-treat population).

Descriptive data were expressed as means and SDs unless otherwise stated or Fisher exact test. The primary and categorical secondary outcome measures were estimated using relative risk (RR). The absolute difference in means of time on the progression to severe disease and lengths of hospitalization between the study groups were determined with a 95% CI. A mixed analysis of variance was used to determine whether the changes in laboratory investigations were the result of interactions between the study groups (between-patients factor) and times (within-patient factor), and $P < .05$ was considered statistically significant. Statistical analyses were performed using IBM SPSS Statistics for Windows, version 22.0 (IBM Corp).

Interim analyses were conducted on the first 150 and 300 patients, with outcome data retrieved on July 13 and August 30, 2021, respectively. The overall level of significance was maintained at $P < .05$, calculated according to the O'Brien-Fleming stopping boundaries. Early stopping would be considered if $P < .003$ for efficacy data. The results were presented to the Data and Safety Monitoring Board, which recommended continuing the study given no signal for early termination.

Subgroup Analyses

Subgroup analyses were predetermined according to COVID-19 vaccination status, age, clinical staging, duration of illness at enrollment, and common comorbidities.

What was the finding?

The modified intention-to-treat population for the primary analysis included 490 patients (98% of those enrolled), with 241 in the intervention group and 249 in the control group (Figure 1). Drug compliance analysis showed that 232 patients (96.3%) in the intervention group completed 5 doses of ivermectin.

Table 1 in the original paper shows the Baseline Demographic and Clinical characteristics of Patients in the Primary Analysis Population. The mean (SD) age was 62.5 (8.7%) years. Both groups had a similar number of male and female patients with 130 women (53.9%) and 111 men (46.1%) in the Ivermectin group and 137 women (55.0%) and 112 (45.0%) in the control group., However number of the male and female patients in the same group was imbalanced with a total of 267 women (54.5%) and 223 men (45.5%). All major ethnic groups in Malaysia were well represented in the study population with Malay being the highest 372 (66.30%) in both groups. 254 patients (51.8%) were fully vaccinated with 2 doses of COVID-19 vaccines and the rest of the patients either received 1 dose of vaccine or were not vaccinated.

Most of both groups had hypertension (369 [75.3%]), followed by diabetes mellitus (262 [53.5%]), dyslipidemia (184 [37.6%]), and obesity (117 [23.9%]). There was an imbalanced number of patients in the intervention versus control group for chronic diseases; Kidney with 28 subjects (11.6%) versus 43 subjects (17.3%) and Cardiac with 37 subjects (15.4%) versus 20 subjects (8.0%), active smoker with 13 subjects (5.4%) versus 7 subjects (2.8%), and malignant neoplasm with 5 subjects (2.1%) versus 9 subjects (3.6%). The mean (SD) duration of symptoms at enrollment was 5.1 (1.3) days. The most common symptoms were cough (378 [77.1%]), fever (237 [48.4%]), and runny nose (149 [30.4%]). Approximately two-thirds of patients had a moderate disease. There were no significant differences in the concomitant medications prescribed for both groups.

Primary Outcome

Among the 490 patients, 95 (19.4%) progressed to severe disease during the study period; 52 of 241 (21.6%) received ivermectin plus standard of care, and 43 of 249 (17.3%) received standard of care alone (RR, 1.25; 95% CI, 0.87-1.80; *P* = .25) (Table 2). Similar results were observed in the intention-to-treat population in the sensitivity analyses (eTable 2 in Supplement 2).

Secondary Outcomes

There were no significant differences between ivermectin and control groups for all the prespecified secondary outcomes (Table 2).

Table 2. Outcomes in Primary Analysis Population

Table 2. Outcomes in the Primary Analysis Population

Outcomes[a]	No. (%) Ivermectin	No. (%) Control	Absolute difference (95% CI)	Relative risk (95% CI)	*P* value
No.	241	249	NA	NA	NA
Primary outcome					
Progression to severe disease (WHO scale 5-9)	52 (21.6)	43 (17.3)	4.31 (−2.69 to 11.31)[b]	1.25 (0.87 to 1.80)	.25
Secondary outcomes					
Time of progression to severe disease, mean (SD), d	3.2 (2.4)	2.9 (1.8)	0.3 (−0.6 to 1.2)[c]	NA	.51
Patients who had mechanical ventilation	4 (1.7)	10 (4.0)	−2.36 (−5.28 to 0.57)[b]	0.41 (0.13 to 1.30)	.17
Patients admitted to ICU	6 (2.5)	8 (3.2)	−0.72 (−3.67 to 2.22)[b]	0.78 (0.27 to 2.20)	.79
All-cause in-hospital mortality	3 (1.2)	10 (4.0)	−2.77 (−5.58 to 0.04)[b]	0.31 (0.09 to 1.11)	.09
Length of stay, mean (SD), d	7.7 (4.4)	7.3 (4.3)	0.4 (−0.4 to 1.3)[c]	NA	.38
Clinical outcome at day 5					
No.	238[d]	247[e]	NA	NA	NA
Complete symptom resolution	122 (51.3)	131 (53.0)	−1.78 (−10.70 to 7.12)[b]	0.97 (0.82 to 1.15)	.72
Normal chest radiography[f]	61 (25.6)	61 (24.9)	0.73 (−7.02 to 8.48)[b]	1.03 (0.76 to 1.40)	.92

Abbreviations: ICU, intensive care unit; NA, not applicable; WHO, World Health Organization.

[a] All outcomes were captured from randomization until discharge from study sites or day 28 of enrollment, whichever was earlier.

[b] Absolute difference in proportion.

[c] Mean difference (mean of ivermectin group minus mean of the control group) with 95% CI.

[d] Three patients withdrew from the study before day 5 after taking at least 1 dose of ivermectin.

[e] Two patients died before follow-up on day 5.

[f] Two patients missed chest radiography on day 5 (n = 245 for control arm).

Subgroup Analyses

Subgroup analyses for patients with severe diseases were unremarkable (Table 3 in the original paper). Among fully vaccinated patients, 22 (17.7%) in the ivermectin group and 12 (9.2%) in the control group developed the severe disease (RR, 1.92; 95% CI, 0.99-3.71; *P* = .06). Post hoc analyses on clinical outcomes by vaccination status showed that fully vaccinated patients in the control group had a significantly lower rate of severe disease (*P* = .002; supporting data in eTable 6 in Supplement 2).

Adverse Events

A total of 55 AEs occurred in 44 patients (9.0%) (Table 4 in the original paper). Among them, 33 were from the ivermectin group, with diarrhea being the most common AE (14 [5.8%]). Five events were classified as SAEs, with 4 in the ivermectin group (2 patients had a myocardial infarction, 1 had severe anemia, and 1 developed hypovolemic shock secondary to severe diarrhea), and 1 in the control group had inferior epigastric arterial bleeding. Six patients discontinued ivermectin, and 3 withdrew from the study owing to AEs. Most AEs were grade 1 and resolved within the study period.

Among the 13 deaths, severe COVID-19 pneumonia was the principal direct cause (9 deaths [69.2%]). Four patients in the control group died from nosocomial sepsis. None of the deaths were attributed to ivermectin treatment.

How much can we take out from this research/paper?

The I-TECH randomised controlled trial (RCT) is an exemplary effort of the Malaysian clinicians and scientists in responding to the issue of Ivermectin as a treatment option for COVID-19. It was amicably completed and reported. This proves to be a good model of scientific response to clinical problems where necessary collaboration and administrative support garnered efficiently to realise the clinical trial.

Based on the post-publication comments on JAMA website and on a myriad of social media platforms, it is possible that the report could be clearer and more comprehensively reported. Some of the approaches used in the conduct of the trials were not usual and considered to be of advanced techniques such as mixed analysis of variance. Others could be misconstrued and confused for other things without specification such as open-label, superiority approach in the sample size determination, modified intention-to-treat analysis, and posthoc analysis. A sufficient and detailed description of these methods would all be helpful to readers.

There are 2 major issues and a few minor issues to be mindful of when appraising this paper. The first is the open-label RCT by design. This may be argued that the primary outcome of progress to severe disease is hard to be biased by any personal preference for being an objective outcome on maintaining SpO_2 at 95% with supplemental oxygen. However, the decision when this happens could be subjective especially when the SpO_2 was hovering around 95% either with patient effort in breathing with or without encouragement, etc. The point is for a RCT to be clear of this kind of doubt/query of performance and detection biases, it would require a double-blind placebo-controlled trial. Nevertheless, it is to bear in mind also that this 'additional' would increase the cost and complexity of the trial especially in the situation where a relatively urgent answer is needed about the efficacy of Ivermectin for COVID-19. The second is the sample size determination that estimated the treatment effect to be 9% absolute different in the proportion of progress to severe disease, but this primary outcome was observed to be at just 4.3%. Revisiting the sample size determination with this rate different would require about 3000 participants in total presuming this is treatment effect holds to the end. Minor issues include lacking sensitivity analyses to examine the consistency of the results by controlling for some of the variables that were imbalanced at baseline. The writing of the report is infused with the flavour of the investigator's prejudice against the studied drug, and less openness to allow the data to speak and be received by the authors. There are inconsistent patterns of the inefficacy of Ivermectin that can be observed in both the primary and secondary outcomes in both groups, even the types of oxygen required to maintain SpO_2. Unfortunately, the conclusions were too much of unwarranted certainty.

The invaluable lessons from I-TECH study re-emphasise meticulous research planning of no compromised measures (double blind in drug trial where outcome measures could be subjected to personal judgments), a more generous sample size estimation or adopting adaptive design [11] in the situation of real uncertainty, sensitivity analyses as the extra miles in statistical analyses, careful interpretation [12] and complete description of methods and reporting would allow the results to go a longer way.

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CURRENT EVIDENCE

April 2022
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Completeness of Clinical Evidence Citation in Trial Protocols: A Cross-sectional Analysis

By: Dr. Sam Yew Sheng Qian (Medical Officer, CRU)

For full reading: https://doi.org/10.1016/j.medj.2022.03.002

Rationale/ Problem Statement	• Clinical trial protocols do not always provide a comprehensive and systematic evidence citation of previous research. • Such incompleteness of evidence in trial protocols causes a few concerns: ✓ Authorities such as the **ethics committee** will be difficult to evaluate the needs, risks, benefits, and ethical issues for a proposed study (1, 2). ✓ **Researchers** are unable to appreciate the significance of the trials. ✓ The practice of **healthcare providers** is not informed by clinical trials. ✓ Redundant trials may lead to waste of resources, causing financial implications to **policymakers, funders, and the public.** ✓ Unnecessary clinical trials may also expose **study participants** to unnecessary research burdens (3).
Study Objectives	• **Primary objective**: To assess the extent to which clinical trial protocols reflected all published and ongoing clinical trials addressing similar clinical hypotheses. • **Secondary objective**: To determine whether clinical trial protocols preferentially cite studies that are randomized, larger, or more similarly designed.
Methods	• **Study design**: Cross-sectional cohort study. • **Search strategies**: Firstly, clinical trial protocols published between 1st January 2018 and 23rd March 2020 was randomly selected from Clinical-Trials.gov database. Secondly, these clinical trial protocols were classified into industry- and non-industry-sponsored trials. Thirdly, using PubMed and ClinicalTrials.gov databases, reference searches were conducted to determine the extent to which the selected clinical trial protocols cited published and ongoing trials with identical intervention-indication pairings. • **Statistical analysis**: The primary outcome (comprehensiveness of citation within clinical trial protocols) was assessed via a) The proportion of clinical trial protocols that cited at least one published and/or ongoing trial of the same intervention-indication pairing; b) Median citation ratio, which was determined by dividing the number of cited trials by the number of citable trials. The secondary outcome (preferential citation) was assessed using Fischer's exact test or Mann-Whitney Test.
Results	• A total of 101 clinical trial protocols were selected from Clinical-Trials.gov database (50 industry-sponsored trials vs 51 non-industry-sponsored trials). • None of the protocols (from both industry- and non-industry-sponsored trials) mentioned that systematic search was conducted for published or ongoing trials of the same drug-indication pairing.

	Primary Outcome	• Of the 50 industry-sponsored trials, 23 (46.0%) cited at least one published trial and 33 (66.0%) cited at least one ongoing trial. Of these, 7 (30.4%) trial protocols did not cite any of the published trials involving the same intervention-indication pairing and 10 (30.3%) protocols did not cite any ongoing trials of the same intervention-indication pairing. The median citation ratio was 0.67. • Of the 51 non-industry-sponsored index trials, 28 (54.9%) cited at least one published trial and 19 (37.3%) cited at least one ongoing trial. Of these, 5 (17.9%) trial protocols did not cite any of the published trials involving the same intervention-indication pairing and 14 (73.7%) protocols did not cite any ongoing trials of the same intervention-indication pairing. The median citation ratio was 0.50. • Of the 73 trial protocols (both industry- and non-industry-sponsored trials) for which cited at least one citable published or ongoing trial involving the same intervention-indication pairing, 56.2% omitted at least one relevant trial and 41.1% did not cite the majority of easily accessible trials. Approximately one in five protocols (21.9%) did not cite any clinical trials that were captured in the reference searches.
	Secondary Outcome	• The selected clinical trial protocols did not preferentially cite trials that were randomized (83.3% of cited studies versus 66.7% of citable studies, p = .23) or trials that had larger sample sizes (median sample size of cited studies: 132.5 versus that of citable studies: 51.0, p = .08). • The selected clinical trials also did not have greater preference to cite studies with more similar design characteristics, including use of the same comparator (60.0% of cited studies versus 46.7% of citable studies, p = .44), same dose (83.3% of cited studies versus 80.0% of citable studies, p > .99), same disease stage (96.7% of cited studies versus 90.0% of citable studies, p = .61), or indication subpopulation (80.0% of cited studies versus 93.3% of citable studies, p = .25).
Conclusion	• Clinical trial protocols undercite relevant trials and do not document systematic searches for relevant clinical trials. • However, there is no preferred citation seen in both industry- and non-industry-sponsored trials.	
Limitations/ Caveats	• The reference searches were only performed using PubMed and ClinicalTrials.gov databases. A more exhaustive search is required using different databases and search strategies. • Some references may be excluded from the selected clinical trials based on scientific justifications (e.g., used irrelevant comparators, had different study designs). The exclusion of such irrelevant studies does not necessarily translate into incompleteness of evidence.	

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WHAT IS A PREDATORY JOURNAL?

CURRENT ISSUE!!!

April 2022
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"Predatory journals & publishers are entities that prioritize self-interest at the expense of scholarship and are characterized by false or misleading information, deviation from best editorial and publication practices, a lack of transparency, and/or the use of aggressive and indiscriminate soli citation practices."

TARGETED RESOURCES:

01. Funders and academic Institutions

Why should funders and academic institutions care about predatory journals?

- Work published in predatory journals is not disseminated responsibly and may not be properly indexed or archived.
- Another common concern is that the work may not undergo peer review (the evaluation of manuscripts by other experts in the same field).
- Work published in these journals may also not comply with rigorous standards for biomedical research protocols or expected reporting quality standards.

02. Researchers and Clinicians

What do researchers need to know about predatory journals?

- False or misleading information.
- Lack of transparency.
- Deviation from best editorial/publication practices
- Use of aggressive and discriminated solicitation practices.

03. Journalist, Patients and The Publics

How do predatory journals impact patients and the public?

- The patients and the public might unintentionally read work that looks like it was published in a proper peer-reviewed journal, but it could be from a predatory journal, and the usual quality checks weren't done.
- Without the right knowledge and training, some journalists who specialize in researching health information can also fall prey to predatory journals by referencing or reporting on of misinformation or low-quality information to the public.

CHECK OUT THE DEFINITION OF PREDATORY JOURNAL BASED ON THREE-PART RESEARCH PROGRAM

Part I: Detailed summary

Here we summarized all the characteristics of predatory journals from the literature

Read more here LINK..

Part II: A Consensus Survey

In three rounds of the survey, experts voted on whether they thought the characteristics we found from the literature were key features of predatory journals

Read more here LINK..

Part III: A Consensus Definition

A consensus definition was established and a plan of action to address predatory journals was formed. This plan included the need to develop a 'one-stop shop' of resources on predatory journals. This website aims to meet this need.

Read more here LINK..

- **Are you facing challenges distinguishing predatory and legitimate journals?**
- **Who do 'predatory journals' prey upon?**
- **Is there any available Journal Transparency Tool?**

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Clinical Trials Registers

Registering clinical trials is important in order to improve clinical trial transparency, reducing publication bias and selective reporting. Besides, it can provide timely updates of the trials, summary results and avoid unnecessary duplications. Most of the scholarly journals also require researchers to register their clinical trials for publications.

Clinical trials registers must be recognised by World Health Organisation (WHO) and International Committee of Medical Journal Editors (ICMJE)

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WHAT ARE THE REGISTERS AVAILABLE?

1. ClinicalTrials.gov

- Database of privately and publicly funded clinical studies conducted around the world.
- Provided by the U.S. National Library of Medicine.
- Contains information about medical studies in human volunteers; mostly are interventional studies and also includes observational studies and programs providing access to investigational drugs outside of clinical trials.
- For more info: Click [HERE]

2. ISRCTN

- Stands for International Standard Randomised Controlled Trial Number.
- Managed by BioMed Central (BMC) (UK).
- Accepts all clinical research studies (whether proposed, ongoing or completed), providing content validation and curation and the unique identification number necessary for publication.
- For more info: Click [HERE]

3. European Union (EU) Clinical Trials Register

- Covers interventional clinical trials that are conducted in the European Union (EU) and the European Economic Area (EEA).
- Also covers clinical trials conducted outside the EU / EEA that are linked to European paediatric-medicine development.
- For more info: Click [HERE]

4. By Countries

Africa	Pan-African Clinical Trials Registry (PACTR)
Australia & New Zealand	Australian New Zealand Clinical Trials Registry (ANZCTR)
Brazil	Brazilian Clinical Trials Registry (ReBEC)
China	Chinese Clinical Trial Registry (ChiCTR)
Cuba	Cuban Public Registry of Clinical Trials (RPCEC)
Germany	German Clinical Trials Register
India	Clinical Trials Registry - India
Iran	Iranian Registry of Clinical Trials
Japan	Japan Registry of Clinical Trial (jRCT)
Korea	Clinical Research Information Service (CRiS)
Lebanon	Lebanese Clinical Trials Registry (LBCTR)
Peru	Peruvian Clinical Trial Registry (REPEC)
Sri Lanka	Sri Lanka Clinical Trials Registry
Thailand	Thai Clinical Trials Registry (TCTR)

How to Search For Registered Trials ?

International Clinical Trials Registry Platform (ICTRP) is a central database containing the trial registration data sets provided by the registries recognized by WHO. It also provides links to the full original records of the registered trials.

ANNOUNCEMENTS

1. MJH series 9: Prospective, Multicenter, Controlled Trial of Mobile Stroke Units. 20th May 2022 by Ms. Nur Faizah
2. Research Colloquium, 18th May 2022
3. International Clinical Trials Day, 19th May 2022. Final Announcement.
4. Common Advanced Statistics in Medical & Health Science. Early Announcement.
5. Statistical tests assumptions. What are they and how to check for them? Early announcement.
6. Research Development Workshop, 25-26 August 2022. Early announcement and calling for registration.
7. The 6th International Clinical Trials Methodology Conference 2022. October 3 – 6, 2022. https://ictmc.org/
8. 7th World Conference on Research Integrity. Cape Town, South Africa, May 29 – June 1 2022. https://wcri2022.org/
9. 9th International Congress on Peer Review and Scientific Publication. September 8 – 10, 2022 Chicago, IL. https://peerreviewcongress.org.
10. International Statistical Institute: Objective & Events

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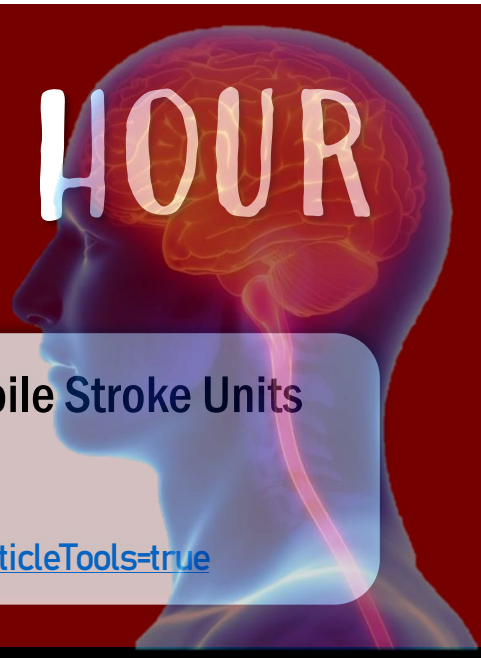

FULL ARTICLE

Prospective, Multicenter, Controlled Trial of Mobile Stroke Units

Click to access full article:
https://www.nejm.org/doi/pdf/10.1056/NEJMoa2103879?articleTools=true

20th MAY 2022 (FRIDAY) | 10.30 – 11.45AM | WEBEX

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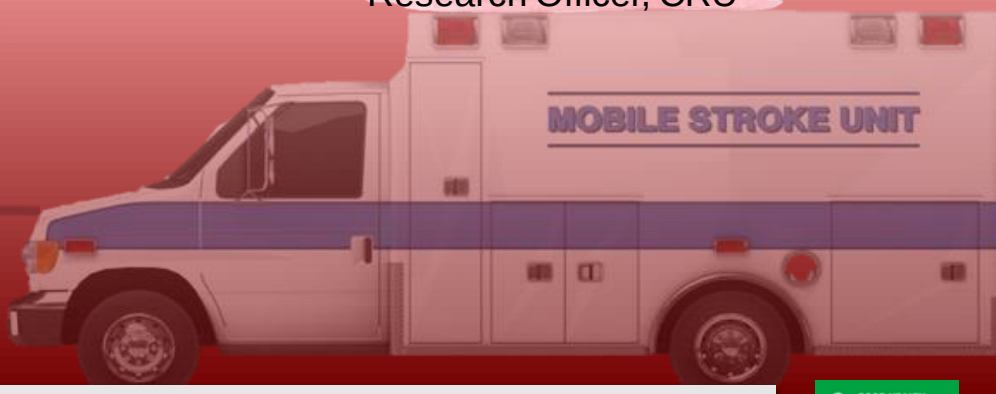
Speaker

Ms. Nurfaizah Saibul
Research Officer, CRU



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First Announcement

RESEARCH Colloquium Series 2

Cisco webex

18th MAY 2022 (WEDNESDAY) | 2:15 PM - 3:00 PM

Title **"Caregiver Burden and health related quality of life among informal caregivers of patient with severe & persistent mental illness"**

LIVE WEBINAR

Presenter

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LIVE WEBINAR

Cisco webex

In conjunction with

INTERNATIONAL CLINICAL TRIALS DAY (ICTD) 2022

CRU, HPUPM will organize a webinar, covering on clinical trials topics

19th May 2022 | 8.45 am - 5.00 pm

Theme: *"Good Science in Clinical Trials"*

Registration fees:

UPM Student / Staff : RM50
Non-UPM Student : RM50
Non-UPM Staff : RM100

Method: Bank Transfer (EFT / CDM)
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Account Number : 14014010156683
Payment Reference: Participant's full name & 'ICTD 2022'

REGISTRATION

For any inquiries, please contact:
Dr. Nur Aazifah Ilham | 03-9769 9761 | aazifah@upm.edu.my
Ms. Faridzatul Syuhada Abdul Rashid | 03-9769 9763 | faridzatul@upm.edu.my

3 GOOD HEALTH AND WELL-BEING

TENTATIVE PROGRAM

Time	Topic	Speaker/Panelist
8.45- 9.00	Welcoming speech by Director of HPUPM	
0900-1000	What is a clinical trial? Q and A	Dr. Yew Sheng Qian (CRU, HPUPM)
1000-1100	How to conduct clinical trials? Q and A	YBhg. Prof. Dato' Dr. Nik Hisamuddin Nik Ab Rahman (Universiti Sains Malaysia)
1115-1215	What is the difference between ITT, PPA, as treated analysis? Q and A	Dr. Najib Majdi bin Yaacob (Universiti Sains Malaysia)
1215-1300	Research in HPUPM • What is the procedure to apply to conduct clinical trials at HPUPM? • Insurance on Trials • Patent Search • Randomisation on Trials	Ms. Faridzatul Syuhada Abdul Rashid Ms. Nurfaizah Saibul Ms. Salwana Ahmad (CRU, HPUPM)
1300-1400	(Lunch Break / Prayer)	
1400-1530	Forum: • Experience by researcher conducting Clinical Trial • How to be a successful researcher in Malaysia?	1. YBhg. Dato' Prof. Dr. Adeeba bt. Kamarulzaman, (University of Malaya) 2. YBhg. Datuk Prof. Dr. Looi Lai Meng (University of Malaya) 3. YBhg. Prof. Dato' Dr. Nik Hisamuddin Nik Ab Rahman (Universiti Sains Malaysia)
1600-1630	Sharing session: Clinical Research Malaysia (CRM) – experience in Phase 1 Clinical Trial	Ms. Nurul Haniza binti Zaini (CRM)

Note: The Organiser reserves the right to cancel or change the topic or trainer of the program, if for whatever reasons beyond its control.

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COMING SOON

COMMON ADVANCED STATISTICS IN MEDICAL & HEALTH SCIENCE

What are they? When to use? How to use them and interpret the outputs?

23rd June 2022

8.15 am– 1.00 pm

LIVE WEBINAR

Cisco webex

ASSOC. PROF. DR. KARUTHAN A/L CHINNA
BSc. (Education), MSc. (Applied Stats), PhD (Mgt)
UCSI University

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- ☑ e-certificate

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3 GOOD HEALTH AND WELL-BEING

TENTATIVE PROGRAM

Time	Title	Speaker*
0815-0820	Introductory speech	AP Dr. CBH
0820-0910	General Linear Model (GLM)	AP Dr. Karuthan
0910-1000	Generalized Estimating Equation (GEE)	
1000-1050	Mixed model (MM) / Generalized Linear Mixed Model (GLMM)	
1050-1100	**Rest**	
1100-1145	Structural Equation Modeling (SEM)	
1145-1245	Examples from analysis with GLM, GEE, MM, GLMM and SEM	
1245-1300	Q&A	

*** CBH ASSOC. PROF. DR. CHEW BOON HOW**

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LIVE WEBINAR

Cisco webex

Second Announcement

Webinar on
STATISTICAL TESTS ASSUMPTIONS

What Are They & How To Check For Them?
How To Rectify The Analysis/Dataset When The Assumption Is Violated?

July 28th, 2022 (Thursday)

8.30 am – 1.00 pm

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BSc. (Education), MSc. (Applied Stats), PhD (Mgt)

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Tentative Program

Opening speech

TOPIC

What it is and why need to be checked?

Parametric Test: T-test, Pearson Correlation
Non-parametric test: Spearman Correlation, Chi-Square, Wilcoxon Rank sum Test, Mann-Whitney U Test

Multivariable linear regression statistical test assumptions

Multivariable logistic regression, Poisson regression and Survival analysis statistical test assumptions

Generalised linear model and Random / Mixed effect model statistical test assumptions

Q&A session

Organised by: Clinical Research Unit, HPUPM

FIRST ANNOUNCEMENT

CLINICAL RESEARCH UNIT (CRU), HPUPM PRESENTS

RESEARCH DEVELOPMENT WORKSHOP

A hybrid workshop to learn and conduct a proper and high-quality clinical, biomedical and health sciences research.

25 – 26 AUGUST 2022 | 8.00 AM – 4.30 PM

BOOK YOUR PREFERRED SLOT

Venue: Hospital Pengajar UPM, Serdang

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1. GO-NOW Hands-on Physical Sessions Participants*

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OR

2. Attendees* (Physical / Online)

Categories of participants	
GO-NOW Participants	To attend with output*
Attendees	Without output

*Output:
Research proposal/ mini review/ peer-review

GO-NOW Participants are required to submit 500 words essay to introduce and argue on a topic of own professional interest or areas to pursue; at least one month before workshop to CRU.

Category	Fees
HPUPM/ FPSK staff/ students	RM 200
Other UPM faculties	RM 300
Non-UPM (Malaysians)	RM 500
Non-Malaysians	USD 500

For pre-registration, scan QR code below
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FIRST ANNOUNCEMENT

TENTATIVE OF THE WORKSHOP

Hour	Talk/ Topic	Tentative speaker
	DAY 1 (25 AUGUST 2022)	
0800 - 0815	***REGISTRATION***	
0815 - 0830	Introduction : Quality healthcare, research, KPI & career advancement	CBH & TDPA
0830 - 0845	**Testimony I :** Personal sharing by an outstanding researcher	TBD
0845 - 0915	***Interactive talk 1***: Understanding the whole research process	CBH
0915 - 1015	***Interactive talk 2:*** Fundamental concepts of clinical epidemiology	CBH
1015 - 1030	***Interactive talk 3:*** Classification of epidemiologic research	CBH
	BREAK	
1045 - 1115	***Interactive talk 4:*** An introduction to qualitative study & designs	Invited speaker
1115 - 1145	***Interactive talk 5:*** Research question, literature review & conceptual framework	CBH
1145 - 1215	***Interactive talk 6:*** An introduction to databases & search strategies	CBH & an invited speaker
1215 - 1245	***Interactive talk 7:*** Theoretical design	CBH
1245 - 1315	***Interactive talk 8:*** Data collection design	CBH
	LUNCH	
1400 - 1430	***Interactive talk 9:*** Sample size estimation	CBH
1430 - 1500	***Interactive talk 10:*** Statistical design	CBH
1500 - 1515	***Interactive talk 11:*** Summary: clinical epidemiology & research methodology	CBH
1515 - 1545	***Interactive talk 12:*** Writing up a study proposal	CBH
1545 - 1615	***Interactive talk 13:*** Ethics clearance for a clinical study	Invited speaker
1615 - 1645	***Interactive talk 14:*** Funding opportunities	Invited speaker
	DAY 2 (26 AUGUST 2022)	
0800 - 0815	***REGISTRATION***	
0815 - 0915	***Interactive talk 15:*** Statistical analysis	CBH
0915 - 1000	***Interactive talk 16:*** Comprehensive reporting, quality writing	CBH
1000 - 1030	***Interactive talk 17:*** Publication process	CBH
	BREAK	
1045 - 1245	***Interactive talk 18:*** Intellectual Property. UPM IP Putra Science Park and the Sistem PRiMS (Putra Research & Innovation Management System)	Invited speaker
	LUNCH	
1400 - 1500	***Interactive talk 19:*** What is evidence-based practice? Appraise the evidence: primary research and systematic reviews & meta-analysis	CBH
1500 - 1530	***Interactive talk 20:*** Summary: a suggested roadmap for clinicians to higher quality in research and publication	CBH
1530 - 1545	**Testimony II :** Personal sharing by an outstanding researcher	TBD
1545 - 1630	**Closure :** Summary & What have you learned? **Q&A**	CBH
	Break & dismissed	
	DAY 3 (AFTER 2-3 MONTHS POST-WORKSHOP) ****For GO-NOW Participants only***	**Facilitator**
0800 - 0830	***REGISTRATION & Intro***	
0830 - 1630	Study proposal presentation	CBH

*CBH: Associate Prof. Dr. Chew Boon How

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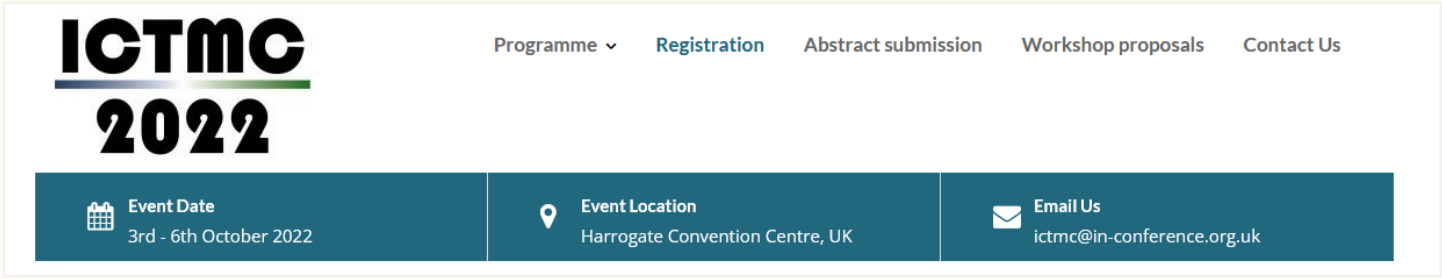
1. The 6th International Clinical Trials Methodology Conference 2022. https://ictmc.org/



2. 7th World Conference on Research Integrity 2022. https://wcri2022.org/

3. UPDATE: ABSTRACT SUBMISSION CLOSED. 9th International Congress on Peer Review and Scientific Publication (Abstract Submission Extended)
https://peerreviewcongress.org/

- Editorial on September 20, 2021. John P. A. Ioannidis et al. Ninth International Congress on Peer Review and Scientific Publication Call for Abstracts. JAMA. 2021;326(13):1265-1267. doi: 10.1001/jama.2021.16596.
- Editorials published 20 September 2021. John P. A. Ioannidis et al. Ninth international congress on peer review and scientific publication—call for abstracts. BMJ 2021;374:n2252. doi: 10.1136/bmj.n2252.

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Objectives :

-To lead, support and promote the international statistical community.
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-To advocate and foster statistical literacy, the use of statistics and data in decision making by governments, businesses and individuals.
-To grow the statistical community in developing countries and help it to be more inclusive.
-To promote an understanding of statistics as a force for improving people's lives.
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