



JAWATANKUASA ETIKA & PENYELIDIKAN PERUBATAN
(Medical Research & Ethics Committee)
KEMENTERIAN KESIHATAN MALAYSIA
d/a Kompleks Institut Kesihatan Negara
Blok A, No 1, Jalan Setia Murni U13/52,
Seksyen U13, Bandar Setia Alam,
40170 Shah Alam, Selangor.



Tel: 03-3362 8888/8205

Ref : KKM/NIHSEC/ P19-1906 (6)

Date: 29- Aug -2019

ONG THIEN JIAN
HOSPITAL SERDANG

Dear Sir / Mdm,

ETHICS INITIAL APPROVAL: NMRR-19-839-46462 (IIR)

An Audit of Time in Therapeutic Range (TTR) in Warfarin Medication Therapy Adherence Clinic (WMTAC) in Hospital Serdang

This letter is made in reference to the above matter.

2. The Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (MOH) has provided ethical approval for this study. Please take note that all records and data are to be kept strictly **CONFIDENTIAL** and can only be used for the purpose of this study. All precautions are to be taken to maintain data confidentiality. Permission from the District Health Officer / Hospital Administrator / Hospital Director and all relevant heads of departments / units where the study will be carried out must be obtained prior to the study. You are required to follow and comply with their decision and all other relevant regulations, including the Access to Biological and Benefit Sharing Act 2017.
3. The investigators and study sites involved in this study are:

HOSPITAL SERDANG
Nurul Afqah Binti Noor Hisham
Ong Thien Jian (Penyelidik Utama)
Ratna Iman Amirah Binti Mohamad
Siaw Sze Hoong
So Seng Hui
TAM AI SUN
Tan Kai Hsin
Wong Ka Yan
4. The following study documents have been received and reviewed with reference to the above study:

Documents received and reviewed with reference to the above study:

1. Study Protocol_Version 2, dated 19-Apr-2019
2. Data Collection Form_Version 1, dated 23-Mar-2019
3. Investigator's documents : Declaration of Conflict of Interest (COI), IA-HOD-IA, and CV:
 - a) Nurul Afqah Binti Noor Hisham
 - b) Ong Thien Jian (Penyelidik Utama)
 - c) Ratna Iman Amirah Binti Mohamad
 - d) Siaw Sze Hoong
 - e) So Seng Hui
 - f) TAM AI SUN
 - g) Tan Kai Hsin
 - h) Wong Ka Yan

5. Please note that ethical approval is valid until **28- August-2020**. The following are to be reported upon receiving ethical approval. Required forms can be obtained from the Medical Research Ethics Committee (MREC) website (<http://www.nih.gov.my/mrec>).
- i. **Continuing Review Form** has to be submitted to MREC within 2 month (60 days) prior to the expiry of ethical approval.
 - ii. **Study Final Report** upon study completion to the MREC.
 - iii. Ethical approval is required in the case of **amendments / changes to the study documents/ study sites/ study team**. MREC reserves the right to withdraw ethical approval if changes to study documents are not completely declared.
6. This study involves the following methods:
- i. **Retrospective**
 - ii. **Secondary data**
7. Please take note that the reference number for this letter must be stated in all correspondence related to this study to facilitate the process.

Comments (if any): NIL

Project Sites:
Hospital Serdang

Decision by Medical Research & Ethics Committee:

(☒) Approved
(☐) Disapproved

Date of Approval : 29 -Aug -2019



DR H.J.H. SALINA ABDUL AZIZ
Chairperson
Medical Research & Ethics Committee
Ministry of Health Malaysia
MMC No: 27117

s.k. HRRC Hospital Rehabilitasi Cheras

MD/Approval2019/Mrecshare

EXPEDITED PROTOCOL/ PATIENT INFORMATION SHEET REVIEW REPORT

NMRR-19-839-46462 (IIR)**An Audit of Time in Therapeutic Range (TTR) in Warfarin Medication Therapy Adherence Clinic (WMTAC) in Hospital Serdang**

Date reviewed 29-Aug-2019

REVIEWED BY HRRC/ OTHER SCIENTIFIC REVIEW COMMITTEES

/ Yes

No

OVERALL VULNERABILITY ASSESSMENT: (tick [/] what is appropriate)

/ Study involves no vulnerable population

Study involves vulnerable population (tick below)

Involvement of minors, adequately protected

Involvement of minors, NOT adequately protected

Involvement of other vulnerable groups, adequately protected

Involvement of other vulnerable groups, NOT adequately protected

OVERALL RISK ASSESSMENT: (tick [/] what is appropriate)

/ Study involves no more than minimal risk

Study involves more than minimal risk (tick below)

Risk represents minor increase over minimal risk

Risk represents more than a minor increase over minimal risk

OVERALL BENEFIT ASSESSMENT: (tick [/] what is appropriate)

/ No prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition

No prospect of direct benefit to individual participants, but likely to yield generalizable knowledge to further society's understanding or the disorder or condition under study

The research involves the prospect of direct benefit to individual participants

DECISION:

/ This study is not more than minimal risk (Approved)

This study is more than minimal risk

Suggest for Expedited Review by Primary Reviewers

Suggest for Full-board Review

COMMENTS:**DECISION BY:**

DR HJH SALINA ABDUL AZIZ

DATED:

29-Aug-2019

SIGNATURE: