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Education programme to help improve patient's knowledge and understanding of atrial fibrillation and warfarin control in Thailand

Submission date
19/11/2020

Recruitment status
No longer recruiting

Registration date
03/12/2020

Overall study status
Completed

Last Edited
08/04/2025

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Anticoagulants ('blood thinners') are needed to prevent stroke and death in patients with atrial fibrillation (AF). AF is the world's most common form of irregular heartbeat, including in Thailand. Anticoagulation is a mainstay treatment in AF patients to prevent strokes. Warfarin is the most commonly used anticoagulant in Thailand, but because it is influenced by many diet and patient factors it can be difficult to achieve good anticoagulation control. In Thailand, because of this, most patients receive inadequate control of their anticoagulation when using warfarin, leading to increased risk of stroke and death.
The aim of this study is to conduct a study in Thai AF patients who have not used an anticoagulant before to evaluate the use of a simple clinical prediction score (SAMe-TT2R2) to help identify those patients likely to have a good response to anticoagulation with warfarin, compared with usual care. Depending on the score participants will be given an educational-behavioural intervention as an addition to their routine care to improve their time in therapeutic range (TTR) on warfarin.

Who can participate?
Men and women aged 18 and over who have been newly diagnosed with non-valvular AF

What does the study involve?
Participants will attend five hospital visits throughout the duration of the study. Each visit will take about 30 minutes and involve physical examinations, blood tests and clinical assessments. Participants will be asked to provide their personal information, medical history and medications they are currently taking. They will be asked to complete a series of questionnaires to measure their life quality and the expenses for medical treatment that they pay for. Participants will also be offered to take part in a sub-study exploring patient satisfaction and acceptance of the TREATS intervention approach.
Eligible participants will be randomly allocated into one of two groups. One group will continue to receive their current usual care; the other group will also continue to receive usual care but also have the extra education (the TREAT intervention) given to them. The intervention group will be provided with additional information on how to use warfarin effectively. This will be

carried out by face-to-face discussion, viewing a video and receiving a booklet. The duration of this activity will take about 30 minutes.

What are the possible benefits and risks of participating?
Participants may not directly benefit from their participation in this study. However, the information from this study could further benefit patients with atrial fibrillation who are treated with Warfarin. There are no additional risks involved over those of standard care.

Where is the study run from?
Chiang Mai University (Thailand)

When is the study starting and how long is it expected to run for?
April 2018 to March 2023

Who is funding the study?
1. Medical Research Council (UK)
2. National Research Council of Thailand (Thailand)
3. Newton Fund (UK)

Who is the main contact?
Prof. Gregory Lip
gregory.lip@liverpool.ac.uk

Contact information

Type(s)
Public

Contact name
Prof Arintaya Phrommintikul

ORCID ID
https://orcid.org/0000-0003-3986-1951

Contact details
Department of Internal Medicine
Faculty of Medicine
Chiang Mai University
Muang Chiang Mai
Chiang Mai
Thailand
50200
+66 (0)5393 6793
arintaya.p@cmu.ac.th

Type(s)
Scientific

Contact name
Prof Gregory Lip

ORCID ID
https://orcid.org/0000-0002-7566-1626

Contact details
Liverpool Centre for Cardiovascular Science
University of Liverpool
William Henry Duncan Building
6 West Derby Street
Liverpool
United Kingdom
L7 8TX
+44 (0)151 794 9020
gregory.lip@liverpool.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
TCTR20180711003, MR/R020892/1, DBG6180009

Study information

Scientific Title
A prospective randomised trial examining the impact of an intensive educational intervention versus usual care on anticoagulation therapy control intervention based on SAMe-TT2R2 score guided strategy in anticoagulant-naïve Thai patients with atrial fibrillation (TREATS-AF)

Acronym
TREATS-AF

Study objectives
Primary hypotheses:
The SAMe-TT2R2 score guided strategy and educational intervention group have more time in the therapeutic range at 12 months than the usual care group.

Secondary hypotheses:
1. The SAMe-TT2R2 score guided strategy and educational intervention group have more time in the therapeutic range at 6 months than the usual care group.
2. The number of thromboembolic and bleeding events in The SAMe-TT2R2 score guided strategy of educational intervention group is less than the usual care group.
3. The number of major adverse cardiovascular events (MACE) in the SAMe-TT2R2 score guided strategy of educational intervention group is less than the usual care group.
4. The SAMe-TT2R2 score guided strategy of educational intervention group have better AF knowledge than the usual care group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/01/2020, Central Research Ethics Committee (CREC) (5th Fl Building 2, The National Research Council of Thailand Paholyothin Rd., Bangkhen, Bangkok 10900, Thailand; +66 (0)2 579 0117; crec_thailand@hotmail.com), ref: CREC053/62BPm

Study design
Multicenter open-label randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Patients diagnosed with new-onset, non-valvular atrial fibrillation and warfarin naïve

Interventions
The aim is to conduct a randomised-controlled trial (RCT) in Thai AF patients who have not used an anticoagulant before to evaluate the use of a simple clinical prediction score (SAMe-TT2R2) to help identify those patients likely to have a good response to anticoagulation with warfarin, compared with usual care. Predicted poorer responders (SAMe-TT2R2 >2) will be given an educational-behavioural intervention based on our previous RCT (TREAT trial) as an addition to routine care to improve their TTR on warfarin.

Method: Open-label RCT; 9-month recruitment period, 12-months follow-up.

Randomization will be done using a web-based platform with blinded allocation. Randomization will be stratified based on centre, sex (male or female) and baseline SAMe-TT2R2 score (0-2, 3-5, 6-8).

Eligible participants will be randomized to one of two groups: usual care vs SAMe-TT2R2 score-guided warfarin (i.e. score 0-2: usual care alone; score >2: usual care plus TREAT educational-behavioural intervention as an adjunct to their regular INR monitoring to improve their TTR on warfarin).

Participants will attend five hospital visits throughout the duration of the study. Each visit will take approximately 30 minutes and involve physical examinations, blood tests and clinical assessments.

Intervention Type
Behavioural

Primary outcome(s)
Time in the Therapeutic Range (TTR) measured by INR level at 12 months

Key secondary outcome(s))

1. Time in the Therapeutic Range (TTR) measured by INR level at 6 months
2. Patients' knowledge measured by the atrial fibrillation knowledge scale questionnaire at baseline, 6 and 12 months
3. Quality of life measured by the EQ-5D-5L questionnaire at baseline, 6 and 12 months
4. Cost-effectiveness measured by CRF questionnaire at 6 and 12 months
5. Cardiovascular event measured by the number of events recorded at 12 months

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. Newly diagnosed AF patients
2. Adults (aged ≥18 years) with ECG-documented non-valvular AF and ≥1 stroke risk factor (based on CHA2DS2VASc score)
3. Warfarin-eligible patients (men with CHA2DS2VASc score ≥1; women with CHA2DS2VASc score ≥2) who are warfarin-naïve (having never taken warfarin) will be considered for inclusion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
320

Key exclusion criteria
1. Any contraindication to oral anticoagulants
2. Prosthetic cardiac valve or significant valvular heart disease with an indication for heart surgery
3. Likelihood of intermittent or permanent discontinuation of warfarin during follow up, e.g. major surgery or post AF ablation
4. Known active malignancy
5. Diagnosed cognitive impairment
6. Any disease likely to cause death within 12 months
7. Unable to provide written informed consent

Date of first enrolment

31/01/2020

Date of final enrolment
31/10/2021

Locations

Countries of recruitment
Thailand

Study participating centre
Maharaj Nakorn Chiang Mai Hospital
Chiang Mai
Thailand
50200

Study participating centre
ChiangRai Prachanukroh Hospital
Chiang Rai
Thailand
57000

Study participating centre
Nakornping Hospital
Chiang Mai
Thailand
50180

Study participating centre
Lampang Hospital
Lampang
Thailand
52100

Study participating centre
Siriraj Hospital
Bangkok
Thailand
10700

Study participating centre
Maharat Nakhon Ratchasima Hospital
Nakhon Ratchasima
Thailand
30000

Study participating centre
Queen Sirikit Heart Center of the Northeast and Srinagarind Hospital
Khon Kaen
Thailand
40002

Sponsor information

Organisation
Chiang Mai University

ROR
https://ror.org/05m2fqn25

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
National Research Council of Thailand

Alternative Name(s)
NRCT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Thailand

Funder Name
Newton Fund

Alternative Name(s)
The Newton Fund, NF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Thailand Chief Investigator Arintaya Phrommintikul (arintayap@gmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		08/10/2024	08/04/2025	Yes	No
Other files			05/04/2024	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes