

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/12/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/04/2025	Condition category Circulatory System	<input type="checkbox"/> 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

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Contact information

Type(s)

Public

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

01/04/2018

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

320

Total final enrolment

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
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Sponsor information

Organisation

Chiang Mai University

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Sponsor type

University/education

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ROR

<https://ror.org/05m2fq25>

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. No additional documents are available.

Intention to publish date

31/03/2023

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?
Other files			05/04/2024	No	No
Results article		08/10/2024	08/04/2025	Yes	No