

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

<b>Submission date</b> 19/11/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/12/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/04/2025	<b>Condition category</b> 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

gregory.lip@liverpool.ac.uk

## Contact information

### Type(s)

Public

### Contact name

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Scientific

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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  $\geq 18$  years) with ECG-documented non-valvular AF and  $\geq 1$  stroke risk factor (based on CHA2DS2VASc score)
3. Warfarin-eligible patients (men with CHA2DS2VASc score  $\geq 1$ ; women with CHA2DS2VASc score  $\geq 2$ ) 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  
Thailand  
40002

## **Sponsor information**

**Organisation**

Chiang Mai University

**Sponsor details**

Faculty of Medicine  
Muang Chiang Mai  
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50200  
+66 (0)5393 6209  
researchmed@cmu.ac.th

**Sponsor type**

University/education

**Website**

<https://www.med.cmu.ac.th/>

**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?
<a href="#">Other files</a>			05/04/2024	No	No
<a href="#">Results article</a>		08/10/2024	08/04/2025	Yes	No