TCTR ID: TCTR20180711003

Overall Recruitment Status: Active, not recruiting

Prospective registration
This protocol was registered before enrollment of the first participant.

OTHER ID:

Tracking Information

First Submitted Date: 11 July 2018

First Posted Date: 11 July 2018

Last Update Posted Date: 04 February 2022

Title

Public Title: A prospective randomised trial examining the impact of an intensive educational intervention versus usual

care on anticoagulation therapy control based on SAMe-TT2R2 score guided strategy in anticoagulant-naive

Thai patients with atrial fibrillation

Acronym: TREATS-AF

Scientific Title: A prospective randomised trial examining the impact of an intensive educational intervention versus usual

care on anticoagulation therapy control based on SAMe-TT2R2 score guided strategy in anticoagulant-naive

Thai patients with atrial fibrillation

Sponsor ID/ IRB ID/ EC ID: CREC053/62BRm

Registration Site: Thai Clinical Trials Registry

URL: https://www.thaiclinicaltrials.org/show/TCTR20180711003

Secondary ID: No Secondary ID

Other Grant/Funding Number; Grantor or Funder: NEWTON FUND DBG6180009

Ethics Review

Board Approval: Submitted, approved
 Approval Number: COA-CREC 007/2020
 Date of Approval: 08 January 2020

Board Name: Central Research Ethics Committee

Board Affiliation: National Research Council of Thailand

Board Contact: Business Phone: 6625790117 Ext. No Data

Business Email: timpika.nimkham.crec@gmail.com

Business Address : Central Research Ethics Committee office5th Floor The National Research Council of

Thailand building 2196 Phaholyothin Road, Ladyao, Chatuchak, Bangkok 10900 Thailand

Sponsor

Source(s) of Monetary or Material Supports: Faculty of Medicine, Chiang Mai University

Study Primary Sponsor: Faculty of Medicine, Chiang Mai University

Responsible Party: Name/Official Title: Arintaya Phrommintikul

Organization: Faculty of Medicine, Chiang Mai University

Phone : 6653936716 Ext. No Data Email : arintayap@yahoo.com

Study Secondary Sponsor: The Thailand Research Fund

Protocol Synopsis

Protocol Synopsis: Anticoagulants are needed to prevent stroke and death in patients with atrial fibrillation (AF). AF is the

world's most common form of irregular heartbeat. Warfarin is the most commonly used anticoagulant in Thailand to prevent strokes, but because it is influenced by many diet and patient factors it can be difficult to achieve good anticoagulation control. Our aim is to conduct a randomized 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. This is open-label, RCT 9 month recruitment period, 12 months follow up. Eligible participants will be randomised to one of 2 groups: Usual care vs. SAMe TT2R2 score guided

warfarin.

URL not available

Health Conditions

Health Condition(s) or Problem(s) Studied: New Atrial Fibrillation patients

Keywords: Atrial Fibrillation SAMe-TT2R2 score Intensive educational intervention Anticoagulation therapy The time

in therapeutic range

Eligibility

Inclusion Criteria: Inclusion criteria:

Patient must meet all of the following inclusion criteria to be eligible for study:

(1) More than 18 years of age

(2) Newly diagnosed non-valvular AF patients

(3) ECG-documented AF

(4) Warfarin-eligible (men with CHA2DS2VASc score more than1; women with CHA2DS2VASc score

more than 2)

(5) Warfarin-naive (No treatment with warfarin within the past 12 months, treatment may have started

within the prior 28 days from randomisation

(6) Able to comply with scheduled visits, treatment plan and laboratory tests

(7) Able to give informed consent and comply with study protocol (with support of a carer)

Gender: Both

Age Limit: Minimum: 18 Years Maximum: N/A (No limit)

Exclusion Criteria: The subjects present with the following criteria will not be included:

(1) Any contraindication to oral anticoagulants(2) Prosthetic cardiac valve or significant valvular heart disease with an indication for heart surgery

(2) Prostrictic Cardiac varve of significant varvinal heart disease with an indication for heart strigery (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.

Accept Healthy Volunteers: No

Status

Overall Recruitment Status: Active, not recruiting

Key Trial Dates Study Start Date (First enrollment) : 31 January 2020 Indicate Type : Actual

Completion Date (Last subject, Last visit): 15 November

2023

Design

Study Type: Interventional
Primary Purpose: Treatment
Study Phase: Phase 0
Intervention Model: Parallel
Number of Arms: 2

Masking: Open Label Allocation: Randomized

Control: No treatment / Standard of care

Study Endpoint Classification: Efficacy Study

Sample size

Planned sample size: 320

Intervantion Arm 1

Intervention name: SAMe-TT2R2 score guided Oral anticoagulation (OAC)

Intervention Type : Active Comparator Intervention Classification : Other

Intervention Description: The SAMe-TT2R2 score was effective in predicting warfarin control whereby

patients with a score>2 had poor control.

Intervantion Arm 2

Indicate Type: Anticipated

Intervention name : usual care
Intervention Type : No Intervention
Intervention Classification : No treatment

Intervention Description: Usual care no other intervention.

Outcome

Primary Outcome

1. Outcome Name: Time in the Therapeutic Range (TTR)

Metric / Method of measurement: INR level

Time point: 12 month

Secondary Outcome

1. Outcome Name: Time in the Therapeutic Range (TTR)

Metric / Method of measurement: INR level

Time point: 6 month

2. Outcome Name: Thromboembolic and bleeding events

Metric / Method of measurement: Number of thromboembolic and bleeding events

Time point: 12 month

3. Outcome Name: major adverse cardiovascular events (MACE)

Metric / Method of measurement : Number of major adverse cardiovascular events (MACE)

Time point: 12 month

4. Outcome Name: Atrial Fibrillation Knowledge

Metric / Method of measurement: Questionnaires

Time point: 6 and 12 month

5. Outcome Name: Economic: Cost Effectiveness

Metric / Method of measurement: Questionnaires

Time point: 6 and 12 month

6. Outcome Name : Economic: Quality of life

 $Metric \, / \, Method \, of \, measurement: \, \, EQ5D5L \, question naires$

Time point: 6 and 12 month

7. Outcome Name: Qualitative: Patient Satisfaction

Metric / Method of measurement : Patient interview analyse by frame matrices

Time point: 6 month

Location

Section A: Central Contact

Central Contact First Name : Arintaya Middle Name : Last Name : Phrommintikul

Degree : M.D. Phone : 66 5393 6716 Ext. : No Data Email : arintayap@yahoo.com

Central Contact Backup First Name : Siriluck Middle Name : Lastname : Gunaparn

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Section B Facility Information and Contact

1. Site Name : Faculty of Medicine, Chiang Mai University

City : Muang Chiang Mai State/Province : Chiang Mai Postal Code : 50200

Country: Thailand Recruitment Status: Completed

Facility Contact First Name : Arintaya Middle Name : Last Name : Phrommintikul

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Facility Contact Backup First Name : Siriluck Middle Name : Last Name : Gunaparn

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Investigator Name First Name : Arintaya Middle Name : Last Name : Phrommintikul

 $\label{eq:continuous_problem} Degree: M.D. \qquad \qquad Role: Principal Investigator$

 $Section \ C: Contact \ for \ Public \ Queries \ (Responsible \ Person)$

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State/Province : Chiang Mai Postal Code : 50200

Country: Thailand Official Role: Study Principal Investigator

Organization Affiliation: Faculty of Medicine, Chiang Mai University

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Arintaya Middle Name : Last Name : Phrommintikul

Degree : M.D. Phone : 66 5393 6716 Ext. : No Data Email : arintayap@yahoo.com

Postal Address : Department of Internal Medicine, Faculty of Medicine, Chiang Mai UniversityMuang Chiang Mai

State/Province : Chiang Mai Postal Code : 50200

Country: Thailand Official Role: Study Principal Investigator

Organization Affiliation: Faculty of Medicine, Chiang Mai University

Deidentified Individual Participant-level Data Sharing

Plan to share IPD: Yes

Plan description: 2 years after publication

Publication from this study

MEDLINE Identifier: No Data

URL link to full text publication : $\,\,\operatorname{No}\,\operatorname{Data}$