TCTR ID : TCTR20180711003

OTHER ID :

Overall Recruitment Status : Active, not recruiting

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

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

1. 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
(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 2022	Indicate Type : Anticipated
	Study Completion Date : 31 December 2022	Indicate Type : Anticipated

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

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 questionnaires
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
	Degree : R.N.	Phone : 66 5393 6716 Ext. : No Data	Email : sgunaparn@gmail.com

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
	Degree : M.D.	Phone : 66 5393 6716 Ext. : No Data	Email : arintayap@yahoo.com
Facility Contact Backup	First Name : Siriluck	Middle Name :	Last Name : Gunaparn
	Degree : R.N.	Phone : 66 5393 6716 Ext. : No Data	Email : sgunaparn@gmail.com
Investigator Name	First Name : Arintaya	Middle Name :	Last Name : Phrommintikul
	Degree : M.D.	Role : Principal Investigator	

Section C : Contact for Public 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

Section D : Contact for Scientific Queries (Responsible Person)

First Name : Arintaya Middle Name : Last Name : Phrommintikul
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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 : No Data