Comparative Study of Oral Anticoagulation in Left Ventricular Thrombi

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03926780	COMPLETED	APRIL 24, 2019	JUNE 11, 2020

STUDY DESCRIPTION

Brief Summary

Left ventricular (LV) thrombus is a common problem that is encountered in patients who survived from a large myocardial infarction, and distal systemic embolization is the main issue in these patients due to its major clinical consequences especially cerebrovascular stroke. Novel oral anticoagulants (NOACs) are now used safely in nonvalvular atrial fibrillation, these agents were shown to be at least as effective as Vitamin K antagonists (VKA) such as warfarin in prevention of systemic embolism, while having an improved safety profile with less bleeding risk. However, the data about their usage for LV thrombi instead of the commonly used VKA are still lacking except for case reports and small case series. The proposed aim of this randomized observational clinical trial is to assess the efficacy of the conventional anticoagulation in the form of warfarin and NOACs in the form of rivaroxaban in the treatment of LV thrombus.

Condition or Disease: Anticoagulants; Increased
Left Ventricular Thrombosis

Intervention/treatment: Drug: Rivaroxaban 20 MG
Drug: Warfarin Sodium

Phase: Phase 3

DETAILED DESCRIPTION

The proposed aim of this randomized observational clinical trial is to assess the efficacy of the conventional anticoagulation in the form of warfarin and NOACs in the form of rivaroxaban in the treatment of LV thrombus.
So patients with actual LV thrombus will be divided into 2 groups, one will receive the traditional therapy which is warfarin with follow up of the INR in order to reach the desired level of 2-3 then follow up every two weeks to determine the time in therapeutic range until the end of the study follow up. The other group will receive oral rivaroxaban 20 mg per day with follow up for the persistence or the disappearance of the LV thrombus one month, three months and 6 months later.
As a secondary and safety end point, any major bleeding will be recorded as well as any thrombo-embolic events

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 79 participants

Intervention Model : Parallel Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: Comparative Study of Oral Anticoagulation in Patients With Left Ventricular Thrombi

Actual Study Start Date: December 2018

Actual Primary Completion Date: May 2020

Actual Study Completion Date: May 2020

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Rivaroxaban 38 Patients with evidence of LV thrombus as assessed by trans-thoracic echocardiography (TTE) will be assigned randomly to receive rivaroxaban in a dose of 20 mg per day	Drug: Rivaroxaban 20 MG 38 Patients with evidence of LV thrombus as assessed by trans-thoracic echocardiography (TTE) will be assigned randomly to receive rivaroxaban 20 mg per day
Active Comparator: Warfarin 38 Patients with evidence of LV thrombus as assessed by trans-thoracic echocardiography (TTE) will be assigned randomly to receive warfarin by the regular starting dose with follow up of the INR to target (2-3)	Drug: Warfarin Sodium 38 Patients with evidence of LV thrombus as assessed by trans-thoracic echocardiography (TTE) will be assigned randomly to receive warfarin sodium by a dose starting from 3 mg per day and titrated accordingly to target an INR of 2-3

OUTCOME MEASURES

Primary Outcome Measures: 1. Presence or absence of left ventricular thrombus as assessed by 2D transthoracic echocardiography [Time Frame: 1 month]
2D transthoracic echocardiography will be done after 1 month of initiation of the anticoagulant in order to assess the presence/absence of the thrombus
2. Presence or absence of left ventricular thrombus as assessed by 2D transthoracic echocardiography [Time Frame: 3 months]
2D transthoracic echocardiography will be done after 3 months of initiation of the anticoagulant in order to assess the presence/absence of the thrombus
3. Presence or absence of left ventricular thrombus as assessed by 2D transthoracic echocardiography [Time Frame: 6 months]
2D transthoracic echocardiography will be done after 6 months of initiation of the anticoagulant in order to assess the presence/absence of the thrombus

Secondary Outcome Measures:	1. Stroke or systemic embolism [Time Frame: Up to 6 months] Any type of stroke or systemic embolism event will be recorded 2. Major bleeding [Time Frame: Up to 6 months] Any major bleeding that may occur according to the criteria of the International Society on Thrombosis and Haemostasis (ISTH) will be recorded

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- Evidence of LV thrombus as assessed by trans-thoracic echocardiography (TTE).

Exclusion Criteria:
- Creatinine clearance less than 50 ml/min.

CONTACTS AND LOCATIONS

Contacts

Locations

Egypt	Andalusia Hospitals	Alexandria

Sponsors and Collaborators

The Young Investigator Group of Cardiovascular Research

Investigator

Study Director :	Haitham Badran, PhD	Assisstant Professor of Cardiology and Angiology, University of Ain Shams, Egypt

MORE INFORMATION

Responsible Party :	The Young Investigator Group of Cardiovascular Research
ClinicalTrials.gov Identifier :	NCT03926780
Other Study ID Numbers :	YIG01201903
First Posted :	April 24, 2019
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Individual Participant Data (IPD) Sharing Statement:	
Plan to Share IPD:	No
Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
Product Manufactured in and Exported from the U.S.:	Yes
Keywords provided by The Young Investigator Group of Cardiovascular Research:	*rivaroxaban* *warfarin left ventricular thrombus*
Additional relevant MeSH terms :	*Thrombosis*