

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of using sandbags and early mobilization in reducing the incidence of the hematoma and Subclinical deep vein thrombosis in patients undergoing cardiac radiofrequency catheter ablation .

Protocol summary

Summary

The objective of this study is to assess of “The effect of using sandbags and early mobilization on hematoma and Sub clinical deep vein thrombosis of patients undergoing cardiac radio-frequency catheter ablation”. Inclusion criteria is candidates for Treatment of cardiac dysrhythmia using cardiac radio-frequency catheter ablation. Exclusion criteria is included Existence of atrial fibrillation, history of deep vein thrombosis, under treatment with thrombolytic drugs, Extensive bleeding or any other complication such as dysrhythmia during and after the radio-frequency catheter ablation procedure. The study population included patients undergoing cardiac radio-frequency catheter ablation referred to Shiraz University of Medical Sciences hospitals and the sample size is 225 people. The intervention consisted of using sandbags on the groin and early mobilization of patients. The intervention start after admission the patients undergoing cardiac radio-frequency catheter ablation in the ward and follow up them until discharge from the hospital (Usually 24 hours). The expected primary result of the study is absence of the hematoma and reduce the incidence of Sub clinical deep vein thrombosis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011631992N1**

Registration date: **2017-03-20, 1395/12/30**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-03-20, 1395/12/30

Registrant information

Name

Mehdi Abbasi Jondani

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 4654 3029

Email address

stud1270652427@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2017-04-04, 1396/01/15

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of using sandbags and early mobilization in reducing the incidence of the hematoma and Subclinical deep vein thrombosis in patients undergoing cardiac radiofrequency catheter ablation .

Public title

The effect of using sandbags and early mobilization on clot formation after ablation catheter removal.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: candidates for Treatment of cardiac dysrhythmia using cardiac radiofrequency catheter ablation; willing to have cooperation in the project; radiofrequency catheter ablation through a vein procedure; age range should be between 18-70 years; systolic blood pressure less than 190 and diastolic blood pressure should be less than 110 mmHg. Exclusion criteria: Unwillingness of participants to continue with the project; Existence of atrial fibrillation; Existence of bleeding disorder; history of deep vein thrombosis before the procedure; cardiac catheterization history over the past month; existence of risk factors causing the increase of deep vein thrombosis incidence such as complete bed rest; loss of consciousness; Existence of advanced heart failure (grade 3 or 4); receiving sedatives during and after the radiofrequency catheter ablation procedure (to avoid having a problem from getting out of bed); treatment with thrombolytic drugs under medical supervision; Extensive bleeding or any other complication such as dysrhythmia during and after the radiofrequency catheter ablation procedure.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **225**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Science

Street address

Headquarters of Shiraz University of Medical Science,
Zand st

City

Shiraz

Postal code**Approval date**

2017-03-12, 1395/12/22

Ethics committee reference number

IR.SUMS.REC.1395.199

Health conditions studied**1****Description of health condition studied**

cardiac arrhythmias

ICD-10 code

I49

ICD-10 code description

Other cardiac arrhythmias

Primary outcomes**1****Description**

Hematoma

Timepoint

Immediately after the departure of catheter sheaths and admission the patients in the ward and follow up them until discharge from the hospital

Method of measurement

Ruler of two-dimensional designed

2**Description**

Subclinical deep vein thrombosis

Timepoint

Immediately after discharge (24 hours after admission)

Method of measurement

Doppler ultrasound

Secondary outcomes

empty

Intervention groups**1****Description**

In the intervention group 1, patients will receive in addition to routine care, intervention using the 2-pound sandbags for 2 hours on the catheter site will be on the groin.

Category

Other

2**Description**

The intervention group 2, in addition to usual care, after 4 hours of bed rest, will be out of bed. That first sitting bedside and then monitoring the vital signs and blood pressure and pulse stability and the absence of complications such as bleeding and hematoma during 4 hours of bed rest, the patients will be out of bed and will walk.

Category

Other

3**Description**

In the control group, the patients after radiofrequency catheter ablation procedure, will receive usual care which includes complete bed rest in the supine position in the bed for 6 to 8 hours without shaking and bending and straightening the involved leg. Also in the first, the vital signs every 15 minutes to 1 hour, then every 30 minutes to 1 hour and then every 4 hours until discharge will be monitored and recorded in the form.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Faghihi hospital

Full name of responsible person

Mehdi Abbasi Jondani

Street address

Shiraz, Fars

City

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Science

Full name of responsible person

Dr Seyed Basir Hashemi

Street addressHeadquarters of Shiraz University of Medical Science,
Zand st**City**

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Science

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Science

Full name of responsible person

Mehdi Abbasi Jondani

Position

MS. Student of medical- surgical Nursing

Other areas of specialty/work**Street address**No. 1690, Taqi abedi Martyr st, Above neighborhood,
Jondan, Ejhiye, Esfahan.**City**

Esfahan

Postal code

8133146131

Phone

+98 31 4654 3029

Fax**Email**

mabsmail23@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Parisa Mansoori

Position

MSc.

Other areas of specialty/work**Street address**

Namazi sq. School of Nursing and Midwifery.

City

Shiraz

Postal code**Phone**

+98 71 3647 4254

Fax**Email**

mansoorip@sums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Science

Full name of responsible person

Mehdi Abbasi Jondani

Position

MS. Student of medical- surgical Nursing

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City

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Postal code

8133146131

Phone

+98 31 4654 3029

Fax**Email**

mabsmail23@gmail.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty