Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Science
Full name of responsible person
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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

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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