Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of continuity of change positioning during and after cardiac radiofrequency ablation on patients' back pain and hemodynamic status

Protocol summary

Summary

After radiofrequency catheter ablation of arrhythmias, patients have to bed rest for 4-6 hours to prevent bleeding and hematoma. However, such a rest may cause back pain in the patients .This study aimed to determine the effects of continuous change in body position during and after the radiofrequency ablation on the back pain and patient’s hemodynamic status. This is a quasi-experimental designed study. Seventy five participants with cardiac arrhythmias, aged 180-80 years who had no known history of back pain and bleeding disorders were randomly assigned to a control group, receiving no change in body position, group A subjected to changes in body position during and after ablation, and group B subjected to changes in body position after ablation. The intensity of pain, blood pressure, heart rate, and extent of bleeding and hematoma were measured. There was no significant difference among the groups in terms of demographic characteristics, blood pressure, heart rate, overall bleeding, hematoma at the entry into the coronary care unit. Compared to the control group, group A had a significantly lower pain score up to 6 hours after the procedure, and group B had a significantly lower pain score up to 4 hours after the procedure. Group B had a significantly higher pain score at 2, 4 and 6 hours post ablation than group A. Changing the body position during and after the ablation procedure would reduce or prevent the back pain without increasing the chance of bleeding and hematoma.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101095578N1**
Registration date: **2012-10-05, 1391/07/14**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2012-10-05, 1391/07/14

Registrant information

Name

Hajar Haghshenas

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4258

Email address

haghshenah@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

The vice chancellor of research technology of Shiraz University of Medical Sciences

Expected recruitment start date

2011-01-21, 1389/11/01

Expected recruitment end date

2011-06-20, 1390/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of continuity of change positioning during and after cardiac radiofrequency ablation on patients' back pain and hemodynamic status

Public title

The effect of changes in patients' body positions on the back pain and hemodynamics

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: eligibility for treatment by radiofrequency catheter ablation; a systolic blood pressure less than 190 mmHg, a diastolic blood pressure less than 110 mmHg. Exclusion criteria were spinal cord disorders; inter-vertebral disk disorders, bleeding disorders; the use of anti-coagulant and analgesic drugs 24 hours prior to the procedure; advanced heart failure, a procedure duration less than one and half and longer than three and half hours; vast bleeding or any other disorders during the procedure; severe decrease of consciousness level; performing ablation procedure through artery; and tranquilizers use during the procedure.
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **75**
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 Sciences
Street address
Central building of Shiraz University of Medical Sciences, Zand st, Shiraz
City
Shiraz
Postal code
Approval date
2011-02-15, 1389/11/26
Ethics committee reference number
CT-89-5392

Health conditions studied

1

Description of health condition studied
patients that have cardiac arrhythmia
ICD-10 code
I49.9
ICD-10 code description
Cardiac arrhythmia, unspecified

2

Description of health condition studied
prolonged bedrest
ICD-10 code
R26.3
ICD-10 code description
Immobility

Primary outcomes

1

Description
pain
Timepoint
immediatly, 2, 4,6 and 24 hr aftrr intervention
Method of measurement
numeric rating scale(NRS)

Secondary outcomes

1

Description
blood pressure
Timepoint
before, immediatly, 2,4,6 and 24 hr after intervention
Method of measurement
standard mercury sphygmomanometer

2

Description
heart rate
Timepoint
befor, immediatly, 2,4,6 and 24 hr after intervention
Method of measurement
by hand during 1 minute

3

Description
amount of bleeding
Timepoint
immediatly, 2,4,6 and 24 hr after intervention
Method of measurement
two-dimension ruler

4

Description
amount of hematoma
Timepoint
immediatly, 2,4,6 and 24 hr after intervention
Method of measurement
two-dimensional ruler

Intervention groups

1

Description
Patients in the control group received routine care including lying on their back for 6-8 hours (including duration of the procedure) with no change in their position.
Category
Prevention

2

Description
Patients in intervention group A did lie on their back during the procedure with the head of their bed tilted up for 15 degree, using a small mattress (3×50×80 cm) under their body and their knee bent for 30 degrees using a small cylindrical pillow. In the first and second hours after the procedure, the continued lying on their back with the head of the bed tilted up for 30 and 45 degrees, respectively. During the two hours post procedure, a small pillow was placed alternatively every 30 minutes under right and left side of the body from shoulder to gluteal. Moreover, they continued to use the small cylindrical pillow under their knees. During the third hour, head of the bed was tilted up 30 degrees and the patients did lie on right and left side for 30 minutes each. Within the forth hour, the patients lied on their side (right or left) for 30 minutes with the head of the bed tilted up for 15 degrees followed by sitting for the next 30 minutes.
Category
Prevention

3

Description
In case group B, the samples were positioned precisely like patients in group A during the procedure, and they were in the routine position after the procedure (without any alteration). The intensity of the back pain, blood pressure, heart rate, the amount of bleeding and hematoma were measured right after the patients entered the CCU and 2, 4, 6 and 24 hours after ablation in 3 groups.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid faghihi and Kowsar hospitals in Shiraz
Full name of responsible person
Hajar Haghshenas
Street address
Shiraz School of Nursing and Midwifery, Zand St, Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor for Research, Shiraz University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Hatam
Street address
Shiraz University of Medical Science, Central Building, Zand Street
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellor for Research, Shiraz University of Medical Sciences
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 Sciences
Full name of responsible person
Parisa Mansoori
Position
MS in nursing- tutor
Other areas of specialty/work
Street address
Fatemeh (P.B.U.H) School of Nursing & Midwifery, Zand St, Namazi square
City

Shiraz
Postal code
Phone
+98 71 1647 4254
Fax
Email
mansoorip@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hosein Nikoo
Position
Assistant professore-Electrophysiologist
Other areas of specialty/work
Street address
Zand St, Medical College
City
Shiraz
Postal code
Phone
+98 71 1235 1087
Fax
Email
mhnmp@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hajar Haghshenas
Position
MS in nursing
Other areas of specialty/work
Street address
Fatemeh (P.B.U.H) School of Nursing & Midwifery, Zand St, Namazi square
City
Shiraz
Postal code
Phone
00
Fax
Email
haghshenahhajar@yahoo.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