

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the effect of early deflation of Trans Radial Band on vascular outcome after transradial coronary angiography in Alzahra hospital in Shiraz 2020

Protocol summary

Study aim

1- Determination and comparison of the effect of routine and early trans radial band evacuation on pain in patients undergoing coronary angiography by radial artery. 2- Determination and comparison of the effect of routine and early trans radial band discharge on hematoma of patients undergoing coronary angiography via radial artery. 3. Determination and comparison of the effect of routine and early trans radial band discharge on radial artery occlusion of patients undergoing coronary angiography via radial artery .

Design

The clinical trial has two intervention and control groups, simple randomization. 70 sample numbers

Settings and conduct

Heart Hospital

Participants/Inclusion and exclusion criteria

1-Men and women 18 years and older 2- Indication of diagnostic angiography, non-emergency treatment, and radial artery prescribed by a physician. 3-Any unexpected condition can lead to disruption of the care process such as myocardial infarction. 4- High levels of consciousness due to hypotension or bleeding 5- Bleeding leads to surgeon intervention 6- Acute and chronic kidney disease

Intervention groups

There will be two groups of control and control in this study. In the control group, The ventilation protocol in this group is the same as the usual protocol in the angiography department. In the control group, after angiography and emptying the sheet and closing the trans radial band, the doctor slowly injected 20 to 25 cc of air into the trans radial band cuff, and after an hour and a half of emptying the cuff again, the same volume of air was evacuated to establish Homeostasis will be returned to the cuff and after 15 to 30 minutes the discharge process will be performed as usual.

Main outcome variables

Hematoma - Radial artery obstruction - Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100919004775N13**

Registration date: **2020-09-18, 1399/06/28**

Registration timing: **prospective**

Last update: **2020-09-18, 1399/06/28**

Update count: **0**

Registration date

2020-09-18, 1399/06/28

Registrant information

Name

Zinat Mohebbi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4254

Email address

zmohebi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of early deflation of Trans Radial Band on vascular outcome after transradial coronary angiography in Alzahra hospital in Shiraz 2020

Public title

effect of early deflation of Trans Radial Band on vascular outcome after transradial coronary angiography

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Men and women 18 years and older Indication of diagnostic angiography, non-emergency treatment, and through the radial artery, as recommended by the physician.

Exclusion criteria:

Any unexpected condition can lead to disruption of the care process such as myocardial infarction Bleeding leads to surgeon intervention Acute and chronic kidney disease vascular problems (burger, diabetes) Acute and chronic liver disease

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **70****Randomization (investigator's opinion)**

Randomized

Randomization description

The random allocation method in this study will be the permutation block method in that A represents the person receiving the intervention and B represents the person who does not receive the intervention. This method is performed by considering 4 blocks so that the total number of 4 permutations is equal to 6. (6 blocks including: ABAB, AABB, BABA, BBAA, ABBA and BAAB) How to use the table of random numbers is that the starting point is selected randomly and 35 numbers are selected randomly (row or column) and the permutation assigned to each number is noted (the order of placement of permutations next to each other in order of Will be left to right) and how to allocate a total of 70 people to 2 groups A, B will be specified.

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**

Ethics committee of Shiraz University of Medical Sciences

Street address

Ferdowsi Street - Sixth Alley

City

Shiraz

Province

Fars

Postal code

7135855975

Approval date

2020-06-02, 1399/03/13

Ethics committee reference number

IR.SUMS.REC.1399.298

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

coronary artery disease

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Hematoma

Timepoint

Once every 15 minutes

Method of measurement

By Easy Scale

2**Description**

pain

Timepoint

Once every 15 minutes

Method of measurement

pain assessment tool

3**Description**

Obstruction

Timepoint

Once every 15 minutes

Method of measurement

Pulse oximeter - Allen test

Secondary outcomes

empty

Intervention groups

1

Description

In this study, the first observation of the control and control groups will be excluded. 35 people are considered for each group. In the control group, after angiography and removal of the sheet and closure of the trans radial band at the puncture site, the physician will inject 20 to 25 cc of air inside the trans radial band cafe. The cuff drain protocol in this group will be 5 thirty years after one and a half hours every quarter hour. At time zero, two hours, four hours, six hours after the sheet was removed in the hand undergoing angiography, hematoma and pain and obstruction were adjusted with the Esay scale to collect the horizontal line hematoma, which shows no need from zero to ten. Pain and pain are considered and the use of Allen test and pulse oximetry for obstruction is examined.

Category

Behavior

2

Description

In this study, the first two observations of each of the control and control groups will be discarded. 35 people are considered for each group. In the control group, the cuff evacuation protocol is the same as the usual protocol in the angiography department.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Heart Hospital in Shiraz

Full name of responsible person

Marjan Karami Khairabad

Street address

Valiasr Street

City

Shiraz

Province

Fars

Postal code

32220078

Phone

+98 71 3222 0078

Email

marjankarami60@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zinat Mohebbi

Street address

Zand St. - Central Building of Shiraz University of Medical Sciences - 7th floor - Vice Chancellor for Research and Technology

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 8232 3571

Email

Vcrdep@sums.ac.ir

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 Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Marjan Karami Khairabad

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Ferdowsi street

City

Gachsaran

Province

Kohgiluyeh-va-Boyerahmad

Postal code

3567978

Phone

+98 71 3222 0078

Email

marjankarami60@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zinat Mohebbi

Position

Assistant Professor of Internal Surgery Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Sadra - Danesh Blvd. - Eram St. - Farhang St. in front of Farhang 3

City

Shiraz

Province

Fars

Postal code

7199414477

Phone

26033641

Email

Mohebbi04@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Zinat Mohebbi

Position

Assistant Professor of Surgical Internal Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Sadra - Danesh Blvd. - Eram St. - Farhang St. in front of Farhang 3

City

Shiraz

Province

Fars

Postal code

7199414477

Phone

+98 26 0336 4171

Email

MOhebbi04@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information on the impact of the secondary outcome on the main outcome is published.

When the data will become available and for how long

One year after the results are published

To whom data/document is available

Participants in research and hospitals

Under which criteria data/document could be used

To participants if they remain in the research until the last stage

From where data/document is obtainable

Call 09173421740 or send an email to marjankarami60@gmail.com.

What processes are involved for a request to access data/document

By referring and sending a request to the email marjankarami60@gmail.com

Comments