

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

the effect of early ambulation on oxidative stress index in patients undergoing coronary angiography

Protocol summary

Study aim

the effect of early ambulation on oxidative stress index in patients undergoing coronary angiography

Design

This study is a type of clinical trial in Shiraz. participants of this study fall into two groups: intervention and control (25 people per group).

Settings and conduct

This study is a type of clinical trial in which 50 patients with angiographic candidate referred to Al-Zahra Heart Hospital in Shiraz will be selected based on the conditions of admission to the study And after obtaining written consent to participate in the study In the form of block crashes, they will fall into two groups: intervention and control (25 people per group). The control group receives routine care in the CCU and post- angiography, In this way, during the whole study hours (6 consecutive hours) they will be lying on their backs, along with the flatness of the head and the flatness of the foot under angiography. The 4kg sandbag will be placed on the catheter entry for 6 hours. In the intervention group, the laying time of the sandbag is reduced from 6 hours to 4 hours, and patients are allowed to move around the bed in a limited way by changing the one-hour position to lying on their backs, right side and left side .

Participants/Inclusion and exclusion criteria

Age below 75 years Conscious satisfaction and willingness to participate in the study Having no back pain angiography for the first time trans femoral coronary angiography

Intervention groups

In the intervention group, the laying time of the sandbag is reduced from 6 hours to 4 hours.

Main outcome variables

Oxidative stress in blood. This index is measured by using blood samples of participating patients and malondialdehyde test with a special kit as an indicator of oxidative stress.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180923041101N2**

Registration date: **2020-11-24, 1399/09/04**

Registration timing: **prospective**

Last update: **2020-11-24, 1399/09/04**

Update count: **0**

Registration date

2020-11-24, 1399/09/04

Registrant information

Name

Majid Najafi Kalyani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4251

Email address

najafikalyani@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the effect of early ambulation on oxidative stress index in patients undergoing coronary angiography

Public title

the effect of early ambulation on oxidative stress index in patients undergoing coronary angiography

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

Age below 75 years Conscious satisfaction and willingness to participate in the study Having no back pain angiography for the first time trans femoral coronary angiography

Exclusion criteria:

People who simultaneously with coronary angiography balloon is also done Lack of cooperation and participation in the study Having underlying disease (including lumbar disc surgery, low back pain, autoimmune disease, cancer) Complications during angiography

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples of this study are assigned to two A, B groups based on the random block method using a table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Clinical nurse and laboratory technician are not aware of assignment to the groups

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

Zand St.

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2020-09-09, 1399/06/19

Ethics committee reference number

IR.SUMS.REC.1399.788

Health conditions studied

1

Description of health condition studied

Coronary Artery Disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Malondialdehyde as an indicator of oxidative stress in the blood

Timepoint

Before and 6 hours after coronary angiography

Method of measurement

Take a patient blood sample and check with a malondialdehyde kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group receives the same routine care, but the sanding time is reduced to 4 hours instead of 6 hours, and patients are allowed limited movement in bed by changing the position for one hour to lying on their back, right side and left side. . Immediately before angiography and 6 hours after it is performed by the researcher, 5 cc of venous blood is taken from each patient to measure oxidative stress index (malondialdehyde), and it is poured into a chelate tube and then transferred to the laboratory where serum is isolated. And stored at -70 ° C until testing.

Category

Diagnosis

2

Description

Control group: The control group received routine care after angiography, including placing a sandbag for 6 hours and absolute rest for 24 hours, immediately before angiography and 6 hours after it was performed by the researcher from each patient with 5 cc of intravenous blood to measure the stress index. The oxidant (malondialdehyde) is taken and poured into a chelate tube and then transferred to a laboratory where the serum is separated and stored at -70 ° C until the test is performed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Heart Hospital

Full name of responsible person

Dr. Peyman Izadpanah

Street address

Sibooyeh St. Astaneh, Alzahra heart hospital

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

Street address

Zand St.

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۷۱۳۳۶ - ۷۱۳۴۸

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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 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

Sara Shamsodini

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Majid Najafi Kalyani

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Position

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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

Analyzed data can be shared after completion of the study as an article.

When the data will become available and for how long

Start of access period 6 months after publication of results.

To whom data/document is available

All of the researchers in Medical Sciences Universities.

Under which criteria data/document could be used

Analysis of data based on statistical software.

From where data/document is obtainable

Dr. Majid Najafi Kalyani

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

Sending request, permission from Ethic Committee, sending data

Comments