

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of stress ball on anxiety in patients under coronary artery angiography

Protocol summary

Study aim

The effect of the stress ball on the anxiety in patients undergoing coronary angiography

Design

The double blinded clinical trial study includes intervention and control groups. Each group consists of 40 people. The randomization will be done lottery by even and odd day.

Settings and conduct

Study in Mazandaran heart center by identifying angiography patients, intervention group and control group will be selected by lottery method on even and odd days. The reason for double blind is that the participant and the researcher are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Full oriented, over 18 years old, not having a known psychology disorder, not taking anti-anxiety drugs, not being addicted to opioids or narcotic analgesic, angiography candidate, first time angiography, angiography through the femoral artery.

Intervention groups

The stress ball is provided to the patient and it will be explained to the patient that this is to relieve the feeling of anxiety and disperse the thoughts of fear and anxiety caused by the angiography process. It will be explained how to use the ball. In the control group, routine care will be done by the ward personnel, both intervention and control groups will receive routine care.

Main outcome variables

Reducing the intensity of anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150916024047N7**

Registration date: **2024-01-14, 1402/10/24**

Registration timing: **prospective**

Last update: **2024-01-14, 1402/10/24**

Update count: **0**

Registration date

2024-01-14, 1402/10/24

Registrant information

Name

Hedayat Jafari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3311 7268

Email address

hjafari@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-07-22, 1403/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of stress ball on anxiety in patients under coronary artery angiography

Public title

The effect of stress ball on anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Full consciousness	Age over 18 years	Angiography for the first time	Angiography trans femoral
Exclusion criteria:			
Taking anti-anxiety drugs			
Having known psychiatric disorder			
Addiction to opioids or analgesics			
Age			
From 18 years old			
Gender			
Both			
Phase			
N/A			
Groups that have been masked			
- Participant - Outcome assessor			
Sample size			
Target sample size: 80			
Randomization (investigator's opinion)			
Randomized			
Randomization description			
To conduct the research, by referring to the Mazandaran heart center and identifying the angiography patients, the people of the test and selection group will be selected on even and odd days, and each group will be placed on the same day, and to determine which group of patients will be on even or odd days. It defines the person. The lottery method is used to place the individual.			
Blinding (investigator's opinion)			
Double blinded			
Blinding description			
The participants were blinded in such a way that each of the intervention and control groups were placed on different days (even and odd) randomly and each group did not know about the implementation of the other group's intervention.			
Placebo			
Not used			
Assignment			
Parallel			
Other design features			
Secondary Ids			
empty			
Ethics committees			
<u>1</u>			
Ethics committee			
Name of ethics committee			
Ethics committee of Mazandaran University of Medical Sciences			
Street address			
Moalem street, Moalem sqaure, Sari			
City			
Sari			
Province			
Mazandaran			
Postal code			

4815696869
Approval date
2023-12-09, 1402/09/18
Ethics committee reference number
IR.MAZUMS.REC.1402.515
Health conditions studied
<u>1</u>
Description of health condition studied
Anxiety
ICD-10 code
F41.9
ICD-10 code description
Anxiety disorder, unspecified
Primary outcomes
<u>1</u>
Description
Anxiety
Timepoint
Before the intervention and 30 minutes after the intervention
Method of measurement
Spielberger Anxiety Scale
Secondary outcomes
empty
Intervention groups
<u>1</u>
Description
Intervention group: The stress ball is available to the patient during angiography. The stress ball is completely soft and has dimensions of 7*7*7 and it is made of jelly that squeezes small bubbles out of the net cover. This ball is available in different and beautiful colors and seven colors, which makes the appearance of these balls attractive. In the current intervention, the ball will be made from the brand Meshball, which has good quality and will not tear when squeezed by the patients.
Category
Treatment - Devices
<u>2</u>
Description
Control group: No intervention will be done for the control group by the researcher.
Category
N/A
Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandaran heart center

Full name of responsible person

Hedayat jafari

Street address

Next to Blood Transfusion Organization, Army Blvd.,
Imam Hossein Square., Sari., Mazandaran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Pedram Ebrahimnejad

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Vice Chancellor for Research Mazandaran University
of Medical Sciences, Moalem St., Moalem Square,
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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

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Hedayat Jafari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

If the names of the people are not identifiable and only the main consequences

When the data will become available and for how long

At the end of the study

To whom data/document is available

For researchers working in Academic And Scientific institutions

Under which criteria data/document could be used

For researchers working in Academic And Scientific institutions

From where data/document is obtainable

hedayat2003@yahoo.com

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

Due to the privacy of the research participants, the data generated during the current study are not publicly available, but are available via Dr. Hedayat Jafari upon reasonable request (hedayat2003@yahoo.com). The Email will be response up to 7 days

Comments