

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of angioplasty procedure movie watching on illness perception and anxiety of patients undergoing elective PCI in Imam Khomeini Hospital, 2015-2016

Protocol summary

Summary

Introduction and objectives: with regarding to that, angioplasty cause anxiety in patients and the anxiety can be affected the mental health, healing and keeping the health situation, we decided to assess the Effect of angioplasty procedure movie watching on illness perception and anxiety of patients undergoing elective PCI in Imam Khomeini Hospital, 2015-2016. Material and methods: this is a single blind clinical trial study that were done on the patients undergone angioplasty procedure in Tehran Imam Khomeini Hospital. The sampling based on random number table. The patients divided to the two groups(each group 30 patients) and the angioplasty procedure film was showed to the only one group(intervention group) after the operation. Matching was done by group matching method. Inclusion criteria was the patients aged between 40-65 years old and exclusion criteria was the history of psychological disorders and hypo or hyperthyroidism. It was filled the check list including demographic data and clinical presentation, Beck 21 anxiety questionnaire and brief illness perception 8 questionnaire for each patient immediately after the intervention and one month later. In the last visit the patients answer the checklist about their complications.

General information

Acronym

PCI : percutaneous coronary intervention

IRCT registration information

IRCT registration number: **IRCT2017021932666N1**

Registration date: **2017-08-13, 1396/05/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-13, 1396/05/22

Registrant information

Name

Maryam Jalalsafari

Name of organization / entity

Tehran University of Medical Scinces

Country

Iran (Islamic Republic of)

Phone

+98 21 6656 0564

Email address

jalalsafari.m@gmail.com

Recruitment status

Recruitment complete

Funding source

Funding sources providing the researcher

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-10-22, 1396/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of angioplasty procedure movie watching on illness perception and anxiety of patients undergoing elective PCI in Imam Khomeini Hospital, 2015-2016

Public title

Effect of angioplasty video show on the patient's anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria was the patients between aged 40 - 65 years old that undergone coronary angiography and candidate for elective PCI. Exclusion criteria were the patients refused cooperation in this study; the history of psychological disorders or hospitalization because of that, hypo or hyperthyroidism without treatment; occurrence of complications after angioplasty or before the second visit; age under 40 or over 65 years old; illiterate persons; the patients with the history of previous angiography; heart failure with ejection fraction below 30% and the CAD patients candidate for medical treatment.

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods St,
Poursina St, north door, Building No.1

City

Tehran

Postal code

1417613151

Approval date

2017-02-07, 1395/11/19

Ethics committee reference number

IR.TUMS.IKHC.REC.1395.1669

Health conditions studied

1

Description of health condition studied

Cardiovascular disease

ICD-10 code

I25

ICD-10 code description

Chronic ischaemic heart disease

Primary outcomes

1

Description

Anxiety

Timepoint

At discharge time and one month later

Method of measurement

Beck anxiety questionnaire

2

Description

Illness perception

Timepoint

At discharge time and one month later

Method of measurement

BIPQ questionnaire

Secondary outcomes

1

Description

Exertional dyspnea

Timepoint

Before and after procedure

Method of measurement

NYHA Class(1/2/3/4)

Intervention groups

1

Description

angioplasty procedure video show in case group

Category

Prevention

2

Description

Not show angioplasty video in control group

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital complex
Full name of responsible person
Dr. Maryam Jalal Safari
Street address
End of Keshavarz Blv, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran Heart center
Full name of responsible person
Dr. Babak Geraiely
Street address
Tehran Heart center, North Kargar St.
City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran Heart center

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
Tehran University of Medical Sciences
Full name of responsible person
Dr. Maryam Jalal Safari
Position
MD/ Cardiology resident
Other areas of specialty/work
Street address
Imam khomeini Hospital complex, Keshavarz blvd.
City
Tehran
Postal code
1419733141
Phone
+98 21 61190
Fax
+98 21 6658 1615
Email
jalalsafari.M@gmail.com

Web page address
Imamhospital@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Maryam Jalal Safari
Position
MD/ Cardiology resident
Other areas of specialty/work
Street address
Imam khomeini Hospital complex, Keshavarz blvd.
City
Tehran
Postal code
1419733141
Phone
+98 21 61190
Fax
+98 21 6658 1615
Email
jalalsafari.M@gmail.com
Web page address
Imamhospital@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Maryam Jalal Safari
Position
MD/ Cardiology resident
Other areas of specialty/work
Street address
Imam khomeini Hospital complex, Keshavarz blvd.
City
Tehran
Postal code
1419733141
Phone
+98 21 61190
Fax
+98 21 6658 1615
Email
jalalsafari.M@gmail.com
Web page address
Imamhospital@tums.ac.ir

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