

# 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 Sciences

###### 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.  
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**Web page address**  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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**Position**  
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Imamhospital@tums.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
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## 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*