

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of premedication on" anxiety", " pain" and" hemodynamic status" of patients undergoing coronary angiography Ganjaviyan Hospital Dezful in 1390: a blind randomized clinical trial interpretations

Protocol summary

Summary

The aim of this study was to determine the effect of premedication on the perception of "anxiety", " pain "and " hemodynamic status" in patients who underwent coronary angiography in Ganjavian Dezful Hospital in 1390. method: The study was designed as a randomized and single- blind trial and all patients gave written informed consent. Following consent a total of 102 patients who scheduled to undergo elective coronary angiography were randomized in to three equal groups (each group 34 patients) based on days of week. The inclusion criteria were Having coronary angiography for the first time; Patients aged 30-70 years; Having just coronary angiography without right heart catheterization; Having no history of invasive procedures before angiography such as Trans Esophageal Echocardiogram. The Exclusion criteria were: History of recent myocardial infarction(during last week); History of severe heart failure, Heart valves disease or congenital heart disease; Hemodynamic instability; History of severe anxiety. Patients sensitivity to pain was measured by pricking the heels with a needle at a distance 5 cm of them. The patients anxiety was measured 8 to 12 hours and half an hour before coronary angiography by VAS criteria. Hemodynamic status was recorded at the same time too. The first group(group A) received 4 mg intravenous Chlorpheniramine and 100mg IV Hydrocortison, the second group (group B) received 5mg IV Diazepam and 100mg IV Hydrocortison, the third group (group C) received 2mg IV Normalsalin solution and 100mg IV Hydrocortison 30 to 60 minutes prior to procedure. Then the patients" anxiety" and" pain" were determined by asking a question during procedure and the level of" anxiety" and pain were measured by VAS criteria. The patients hemodynamic were recorded every 5 minutes for four times. The patients pain level was measured at arrival time to the ward and 2-4-6 after

coronary angiography by VAS criteria. The hemodynamic status was recorded every 15 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012071010235N1**

Registration date: **2012-12-31, 1391/10/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-12-31, 1391/10/11

Registrant information

Name

Hamideh Mashalchi

Name of organization / entity

Ahvaz Jondishapor University of Medical Sciences, Ahvaz Jondishapor University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 65 2235 6552

Email address

hamidehmashalchi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapor University of Medical Sciences and Vice chancellor for research, Arvand University of Medical Sciences

Expected recruitment start date

2012-05-30, 1391/03/10

Expected recruitment end date

2012-06-30, 1391/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of premedication on" anxiety"," pain" and" hemodynamic status" of patients undergoing coronary angiography Ganjaviyan Hospital Dezful in 1390: a blind randomized clinical trial interpretations

Public title

The effect of premedication on" anxiety"," pain" and" vital signs" of patients with coronary angiography

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having coronary angiography for the first time ; Patients aged 30-70 years ; Having just coronary angiography without right heart catheterization ; Having no history of invasive procedures before angiography such as Trans" Esophageal Echocardiogram". Exclusion criteria: History of recent myocardial infarction(during last week); History of severe heart failure, Heart valves disease or congenital heart disease; Hemodynamic" instability" ; History of severe anxiety.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **102**

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**

Ahvaz Jundishapur of Medical Sciences ethics committee.

Street address

Research Vice-Chancellor of Ahvaz Jundishapur University of Medical Sciences, Golestan boulevard , university campus

City

Ahvaz

Postal code

6135715794

Approval date

2012-05-26, 1391/03/06

Ethics committee reference number

495-ETH

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

cardiac catheterization

ICD-10 code

I20

ICD-10 code description

Angina pectoris

Primary outcomes**1****Description**

Anxiety severity

Timepoint

8-12 hours and half an hour before coronary angiography and during coronary angiography.

Method of measurement

Whether having anxiety by asking a question and anxiety level by VAS criteria.

2**Description**

Pain severity

Timepoint

During Angiography and after in time of arrival and 2,4,6 hours after coronary angiography

Method of measurement

Whether Having pain by asking a question and pain level by VAS criteria.

3**Description**

Hemodynamic status

Timepoint

8-12 hours and half an hour before coronary angiography and every 5 minutes during procedure then every 15 minutes after procedure.

Method of measurement

By Control pulse, respiration, temperature, systolic and diastolic blood pressure

Secondary outcomes

1

Description

Measure rate sensitivity to pain

Timepoint

One hour before injection of the premedication

Method of measurement

The heels with a needle at a distance 5 cm

Intervention groups

1

Description

In group A the hemodynamic status and anxiety level were recorded 8 to 12 hours and half an hour prior to coronary angiography, then they recieved 4mg IV Chlorpheniramine and 100mg IV Hydrocortizon, 0/5 to 1 hour before procedure as premedication. The anxiety level and pain level and hemodynamic status were recorded every 5 minutes during coronary angiography. The pain level was measured at arrival time to ward and 2-4-6 hours after procedure, and the hemodynamic status was recorded every 15 minutes.

Category

Treatment - Drugs

2

Description

In group B the hemodynamic status and anxiety level were recorded 8 to 12 hours and half an hour prior to coronary angiography, then they recieved 5mg IV Diazepam and 100mg IV Hydrocortizon, 0/5 to 1 hour before procedure as premedication. The anxiety level and pain level and hemodynamic status were recorded every 5 minutes during coronary angiography. The pain level was measured at arrival time to ward and 2-4-6 hours after procedure, and the hemodynamic status was recorded every 15 minutes.

Category

Treatment - Drugs

3

Description

In group C the hemodynamic status and anxiety level were recorded 8 to 12 hours and half an hour prior to coronary angiography, then they recieved 2mg IV Normalsalin and 100mg IV Hydrocortizon, 0/5 to 1 hour before procedure as premedication. The anxiety level and pain level and hemodynamic status were recorded every 5 minutes during coronary angiography. The pain level was measured at arrival time to ward and 2-4-6 hours after procedure, and the hemodynamic status was recorded every 15 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gangavian Hospital in Dezful

Full name of responsible person

Hamideh Mashalchi

Street address

Dezful, Andimeshk road

City

Dezful

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice-Chancellor of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Mostafa Fegghi

Street address

Research Vice-Chancellor of Ahvaz Jundishapur University of Medical Sciences, Golestan boulevard , university campus

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Vice-Chancellor of Ahvaz Jundishapur University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Arvand International Division, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr Javaheri

Street address

Arvand International Division, International Airport, Abadan

City

Abadan

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Arvand International Division, Ahvaz Jundishapur University of Medical Sciences
Proportion provided by this source
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
 Medical and Health Services, Ahwaz Jondi Shapur - The International Arvand
Full name of responsible person
 Fakharzadeh Leyla
Position
 Master and member of the Faculty of Nursing
Other areas of specialty/work
Street address
 Abadan, Taleghani Hospital, Nursing Abadan
City
 Abadan
Postal code
 post box517
Phone
 00
Fax
 +98 63 1333 5363
Email
 Fakharzadehl@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
 Medical and Health Services, "Ahwaz Jondi Shapur" - the unit International Arvand
Full name of responsible person
 Fakharzadeh Leyla
Position
 Master and member of the Faculty of Nursing
Other areas of specialty/work
Street address

Abadan Faculty of Nursing, "Taleghani Hospital", "Abadan"
City
 Abadan
Postal code
 post box517
Phone
 00
Fax
 +98 63 1333 5363
Email
 Fakharzadehl@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
 Ahvaz Jondishapor University of Medical Sciences, "Ahvaz Jondishapor" University of Medical Science
Full name of responsible person
 Hamideh Mashalchi
Position
 Nursing student
Other areas of specialty/work
Street address
 Mahshahr, "Phase 2", "Roshdiye Blvd", "Building Eram1"
City
 Mahshahr
Postal code
Phone
 +98 65 2235 6552
Fax
 +98 65 2266 2971
Email
 Hamidehmashalchi@yahoo.com;
 Hasanpirmand@yahoo.com;
 Fakharzadehl@yahoo.com
Web page address

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