

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of limited and controlled visitation on the anxiety of patients admitted to the cardiac critical care unit

Protocol summary

Summary

Objectives of the study: Comparing the effects of "controlled visitation" and "limited visitation" on the anxiety levels of patients admitted to CCU of "Shahid Rajaee Hospital of Gachsaran". Design: This study is a after and before quasi-experimental research with a control group. Study population: patients admitted for angina (pectoris) to CCU of "Shahid Rajaee Hospital of Gachsaran" who are conscious with no history of psychiatric illness or psychoactive drug abuse. Patient group: 60 patients who meet the above mentioned criteria will be selected for this study. Intervention: 30 patients selected randomly from the patient group will be allowed to have "controlled visitation" twice daily for one hour and their anxiety level will be measured before and after intervention using Spielberger Inventory. In the controlled group the "limited visitation" policy will be applied which is routinely applied in CCU of "Shahid Rajaee Hospital of Gachsaran" and their anxiety levels will be measured during the first twelve hours of admission and 48 hours after it. Finally the anxiety levels of the patients in the intervention and control group will be compared. Outcome: patient anxiety.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110524898N1**

Registration date: **2016-08-27, 1395/06/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-27, 1395/06/06

Registrant information

Name

somaye bashti

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3333 5450

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s.bashti@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Committee of Ardabil University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of limited and controlled visitation on the anxiety of patients admitted to the cardiac critical care unit

Public title

Comparison of the effects of limited and controlled visitation on anxiety of patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The subject is: Able to communicate; Conscious and aware of time, place and person; Clinically diagnosed with angina (pectoric) and admitted for it;

Willing to participate. Exclusion criteria: The patient: Has a history of psychiatric illness or psychoactive drug abuse; Is likely to be admitted to CCU in less than 24 hours; Is unable to comply with the protocol of this study; Is moved from a different ward.

Age

No age limit

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)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ardabil University of Medical Sciences

Street address

Ardabil, Veterans Square, University Avenue, University of medical sciences

City

Ardabil

Postal code

5618953141

Approval date

2015-10-27, 1394/08/05

Ethics committee reference number

ir.arums.rec.1394.58

Health conditions studied

1

Description of health condition studied

Angina (Pectoris)

ICD-10 code

I25-I20

ICD-10 code description

Ischaemic heart diseases

Primary outcomes

1

Description

Anxiety

Timepoint

Before intervention and 48 hours after it

Method of measurement

Spielberger Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: 30 patients selected randomly from the patient group will be allowed to have "controlled visitation" twice daily for one hour and their anxiety level will be measured before and after intervention using Spielberger questionnaire.

Category

Other

2

Description

In the control group the "no visitation" policy will be applied which is routinely used in CCU of "shahid rajaee hospital of gachsaran" and their anxiety levels will be measured during the first twelve hours of admission and 48 hours after it. Finally the anxiety levels of the patients in the intervention and control group will be compared.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaee Hospital of Gachsaran

Full name of responsible person

Masoumeh Aghamohamadi

Street address

Previous Building Health Region, Between Saddi and Hafez Sq., Shohada Highway, Ardabil

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research Ardabil University of

medical sciences

Full name of responsible person

Masoumeh Aghamohammadi

Street address

Previous Building Health Region, Between Saddi and Hafez Sq., Shohada Highway, Ardabil

City

Ardabil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice President of Research Ardabil University of medical sciences

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

Ardabil University of medical sciences

Full name of responsible person

Somaye Bashti

Position

student of MSC in critical care nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

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PhD and Assistant Professor Nursing

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Rajai Hospital- Gachsaran

Full name of responsible person

Somayeh Bashti

Position

nursing expert

Other areas of specialty/work

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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