Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A clinical trial to compare orientation program and educational pamphlet on anxiety in patients who need to undergo MRI

Protocol summary

Summary

This study is a randomized single-blinded, controlled clinical trial, aimed to compare orientation program and educational pamphlet on anxiety in patients who need to undergo MRI. This study will be carried out on 90 patients referred to the MRI center of 22-Bahman Hospital according to inclusion criteria. Randomization will be done using sealed envelopes. In Intervention group 1, Pamphlet about the definition MRI, preparation before the procedure, explanations about all the steps before, during and after the MRI, ways to reduce anxiety during the procedure and explaining the potential risks and benefits of MRI are given to patients in a simple and understandable way. In Intervention group 2, educational content similar to Intervention group 1 will be provided by researcher to every patient through face-to-face education. The patients will be given enough time to express their feelings and ask any questions they might have. At the end, the patients will be familiarized with MRI room and MRI machine. The control group only will receive routine care and they complete Spielberger Anxiety and demographic questionnaires. Patients' anxiety prior to MRI will be reaffirmed using Spielberger anxiety questionnaire. All patients in intervention groups will complete demographic and Spielberger Anxiety questionnaires before and after the intervention. The main outcome will be level of anxiety.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016061228404N1**
Registration date: **2017-04-02, 1396/01/13**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-02, 1396/01/13

Registrant information

Name

Habib Shareinia

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Gonabad University of Medical Sciences

Expected recruitment start date

2016-05-12, 1395/02/23

Expected recruitment end date

2016-08-20, 1395/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare orientation program and educational pamphlet on anxiety in patients who need to undergo MRI

Public title

The effect of orientation program and educational pamphlet on anxiety

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: need for MRI; age over 18 years; having no history of previous MRI; not use any kinds of hypnotics and sedatives; not having been hospitalized. Exclusion criteria:having history of known psychiatric disorders; being addict to any kinds of drugs

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization will be done using sealed envelopes

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad

City

Gonabad

Postal code

05157223028

Approval date

2016-05-11, 1395/02/22

Ethics committee reference number

IR.GMU.REC.1395.31

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Anxiety state

Primary outcomes

1

Description

Anxiety

Timepoint

Before and After training

Method of measurement

Spielberger's State-Trait Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In Intervention group 1, Pamphlet about the definition MRI, preparation before the procedure, explanations about all the steps before, during and after the MRI, ways to reduce anxiety during the procedure and explaining the potential risks and benefits of MRI are given to patients in a simple and understandable way.

Category

Prevention

2

Description

In Intervention group 2, educational content similar to Intervention group 1 will be provided by researcher to every patient through face-to-face education. The patients will be given enough time to express their feelings and ask any questions they might have. At the end, the patients will be familiarized with MRI room and MRI machine.

Category

Prevention

3

Description

The control group only will receive routine care

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Gonabad 22 Bahman haspital

Full name of responsible person

Habib Shareinia

Street address
Gonabad 22 Bahman hospital, Naser khosro Ave, Gonabad
City
Gonabad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Gonabad University of Medical Sciences
Full name of responsible person
Dr. Ali Mohammadpour
Street address
Gonabad University of Medical Sciences, Next to the Asian Road, Gonabad
City
Gonabad
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Gonabad 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

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Person responsible for updating data

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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