

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Effect of Benson relaxation method versus no intervention on anxiety and hemodynamic status of patients before surgery: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of Benson relaxation method on anxiety and hemodynamic status of patients before surgery **Design:** A randomized clinical trial **Setting and conduct:** All patients who are candidate for angiography, angioplasty, coronary artery bypass graph, or abdominal surgery who refer to Ekbatan or Beasat hospitals in Hamadan city will be enrolled in to the trial if they are eligible. **Inclusion and exclusion criteria:** The patients of 18 to 65 years of will be enrolled. Patients who have any one of the following problems will be excluded: (a) hearing loss; (b) muscle paralysis; (c) known psychiatric disease; (d) negative history of previous muscle relaxation; (e) understanding Persian language; (f) no addiction to narcotic, sedative, or alcohol. **Intervention:** Routine pre-operative medications and procedures plus listening to audio files for half an hour using Benson relaxation method through headphones an hour before surgery. **Control:** Routine pre-operative medications and procedures only. **Primary outcome:** Measuring anxiety using the Hospital Anxiety Inventory consists of seven questions based on the four-choice Likert's scale (scoring of 0 to 3) with a minimum score of zero and a maximum score of 21. Mean score of 0-7 means no anxiety; 8-10 means intermediate anxiety; and 11 or above means a suspected anxiety disorder. The anxiety was evaluated in the patients 8 to 12 hours before the intervention and a half an hour before the surgery. **Secondary outcome:** The secondary outcomes of interest include: (a) measuring systolic and diastolic blood pressure using a heart monitoring device, 8 to 12 hours before the intervention and a half an hour before surgery; (b) measuring heart rate pressure using a heart monitoring device, 8 to 12 hours before the intervention and a half an hour before surgery; (c) measuring respiratory rate pressure using a heart monitoring device, 8 to 12 hours before the intervention and a half

an hour before surgery

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312249014N19**

Registration date: **2014-01-06, 1392/10/16**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-01-06, 1392/10/16

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-08-22, 1393/05/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Benson relaxation method versus no intervention on anxiety and hemodynamic status of patients before surgery: a randomized clinical trial

Public title
Effect of Benson relaxation method versus no intervention on anxiety and hemodynamic status of patients before surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion and exclusion criteria: The patients of 18 to 65 years of will be enrolled. Patients who have any one of the following problems will be excluded: (a) hearing loss; (b) muscle paralysis; (c) known psychiatric disease; (d) negative history of previous muscle relaxation; (e) understanding Persian language; (f) no addiction to narcotic, sedative, or alcohol.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid

Fahmideh Ave
City
Hamadan
Postal code
6517838695

Approval date
2013-12-08, 1392/09/17

Ethics committee reference number
P/16/35/9/2933

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Measuring anxiety

Timepoint

8 to 12 before the intervention and half an hour before the surgery

Method of measurement

Using the Hospital Anxiety Inventory consists of seven questions based on the four-choice Likert's scale (scoring of 0 to 3) with a minimum score of zero and a maximum score of 21. Mean score of 0-7 means no anxiety; 8-10 means intermediate anxiety; and 11 or above means a suspected anxiety disorder

Secondary outcomes

1

Description

measuring systolic and diastolic blood pressure

Timepoint

8 to 12 before the intervention and a half hours before surgery

Method of measurement

using a heart monitoring device

2

Description

measuring heart rate pressure

Timepoint

8 to 12 before the intervention and a half hours before surgery

Method of measurement

using a heart monitoring device

3

Description

measuring respiratory rate pressure

Timepoint

8 to 12 before the intervention and a half hours before surgery

Method of measurement

using a heart monitoring device

Intervention groups

1

Description

Routine pre-operative medications and procedures plus listening to audio files for half an hour using Benson relaxation method through headphones an hour before surgery

Category

Prevention

2

Description

Routine pre-operative medications and procedures only

Category

Other

Recruitment centers

1

Recruitment center**Name of recruitment center**

Ekbatan and Beasat hospitals

Full name of responsible person

Fatemah Ashtarani

Street address

Ekbatan hospital, Taleghani Ave, Jihad Square,-
Beasat hospital Shahed square,

City

Hamadan

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

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 the Technology, Hamadan
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**

School of Nursing and Midwifery, Hamadan University
of Medical Sciences

Full name of responsible person

Fatemeh Ashtarani

Position

MSc

Other areas of specialty/work**Street address**

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Person responsible for updating data

Contact

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