Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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
Ekbatab hospital, Taleghani Ave, Jahad 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
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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