Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative study of ear plug versus music on anxiety reduction in elective cesarian section patients undergoing spinal anesthesia

Protocol summary

Summary

The main objective is to compare the effect of ear pluge and music reducing anxiety in patients candidate for elective cesarean under spinal anesthesia. This study is a single blind prospective clinical trial and is conducted on 90 pregnant women (with no history of psychiatric and hearing problems) whom candidate elective cesarean under spinal anesthesia enrolled randomly to three groups (control group, ear plug group and music group). Patients underwent trait anxiety inventory score (STAI-TA) testing before surgery to determine the property based anxiety. Before and after intervention, anxiety is measured and recorded by using Ashpyl Berger questionnaires. Data is then statistically analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205201617N6**
Registration date: **2013-05-07, 1392/02/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-05-07, 1392/02/17

Registrant information

Name

Mansour Choubsaz

Name of organization / entity

Imam Reza Hospital

Country

Iran (Islamic Republic of)

Phone

+98 83 1724 6708

Email address

mchoubsaz@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences and health Services

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of ear plug versus music on anxiety reduction in elective cesarian section patients undergoing spinal anesthesia

Public title

Ear plug versus music on anxiety reduction in elective cesarian section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ASA class1 & 2; pregnant women candidates for elective cesarean section second delivery; agree to participate in the study. Exclusion criteria: a history of psychiatric disease or psychotropic drug consumption hearing.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

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

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Kermanshah University of Medical Sciences
Street address
Pro-Vice-Chancellor for Research, Kermanshah University of Medical Sciences Kermanshah Kermanshah Iran, Islamic Republic Of
City
Kermanshah
Postal code
Approval date
2012-12-29, 1391/10/09
Ethics committee reference number
45283

Health conditions studied

1

Description of health condition studied
anxiety
ICD-10 code
F41
ICD-10 code description
anxiety disorders

Primary outcomes

1

Description
Anxiety
Timepoint
0, 1 and 6 hours
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Blood pressure
Timepoint
0 and 30 minutes and 1 and 6 hours
Method of measurement
Automated blood pressure monitor

2

Description
Heart rate
Timepoint
0 and 30 minutes and 1, 2 and 6 hours
Method of measurement
Pulse oximetry

Intervention groups

1

Description
The first group in added to common medical care , Patients ear is occlude with foam earplugs protection
Category
Other

2

Description
The control group received usual medical care
Category
N/A

3

Description
The third group in added to common medical care hear calming music by headphones
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Kermanshah University of Medical Sciences and Health Services IMAM REZA hospital
Full name of responsible person
Dr. Farid Najafi
Street address
Imam Reza hospital-Zakaria boulevard
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences and health Services q
Full name of responsible person
Mohammad Reza Nikbakhat
Street address
Kermanshah University of Medical Sciences and health Services
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah University of Medical Sciences and health Services q
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
Kermanshah University of Medical Sciences and Heaith Services
Full name of responsible person
Azadeh Bayat
Position
MD, resident of Anesthesiology
Other areas of specialty/work
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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