Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial the effect of sound therapy on severity of pain in women after cesarean section, by spinal anesthesia compared with patients with routine care

Protocol summary

Summary

The purpose of this research is the study of the effect of sound therapy on severity of pain in women. This measurement is done in 48 hours after surgery using VAS. The sound played for intervention group has no voice, sound tool, and was taken from nature. The population of the study: All pregnant women referred to Jahrom Hospital of Motahari for caesarian section with spinal anesthesia who do not have exclusion criteria. The sample size is estimated 57. Before surgery, Patients will categorize into three groups by throwing dice into 1) control, 2) headphone (without playing any sounds) and 3) the intervention with playing sounds. In the first group the patient will receive the Indomethacin suppository and their scores would be recorded without any procedure. In the second group, upon entering the ward, besides using suppository, the headphone is worn without playing any sound. In the third group, using headphone and playing sounds pain score will record. The night before surgery the patient will be met and demographic information will be completed. After the surgery and reentering to the ward, the necessary intervention will be performed every 6 hours for 20 minutes, and then pain severity is measured. All patients should sign informed consent before participation in the study. Patients with chronic pains and cancer, hearing and verbal impairment, having mental and psychological problems will be excluded from the study. It is expected that the intervention leads to reduction of pain severity and increases satisfaction from this non-pharmacologic method of pain management.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015020114049N2**

Registration date: **2015-07-07, 1394/04/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-07-07, 1394/04/16

Registrant information

Name

Ali Abbasi Jahromi

Name of organization / entity

Jahrom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 79 1334 1501

Email address

abbasija@jums.ac.ir

Recruitment status

Recruitment complete

Funding source

Jahrom University of Medical Sciences

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial the effect of sound therapy on severity of pain in women after cesarean section, by spinal

anesthesia compared with patients with routine care

Public title
The effect of Sound Therapy on Pain severity after cesarean section
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: All the patients who are going to do cesarean section at Motahari hospital affiliated to Jahrom University of Medical Sciences can receive spinal anesthesia. Informed consent for participation in this study is the main criteria for inclusion. Exclusion criteria: Not interested in nature sounds, education under primary school, chronic pains and cancer, Hearing or speech impairment, lack of mental and psychological health, chronic use of painkillers and narcotics, Unstable hemodynamic status, expressing disagreement for continuing the research.
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **57**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Double blind method has been used in this study so that the 1- The volunteer and 2- The person who records pain are not aware of measurement methods in intervention and control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Jahrom University of Medical Sciences
Street address
School of Nursing and Midwifery, Motahhari Blvd, Jahrom
City
Jahrom
Postal code
Approval date
2015-02-04, 1393/11/15
Ethics committee reference number
JUMS.Rec.1393.101

Health conditions studied

1

Description of health condition studied
Scores Pain after Sound Therapy
ICD-10 code
R52.0
ICD-10 code description
Severe abdominal pain

Primary outcomes

1

Description
Pain in the Abdomen and Pelvis
Timepoint
Every 6 hours after surgery Within 48 hours(2 days)
Method of measurement
On base of VAS

Secondary outcomes

1

Description
Vital Signs
Timepoint
Every 6 hours after surgery Within 48 hours(2 days)
Method of measurement
Monitoring Blood pressure, Heart Rate, Temperature, Breathing

Intervention groups

1

Description
In the Control group the patient will receive Indomethacin suppository upon entering to ward and pain scores and Hemodynamic signs would be recorded without any further action.
Category
N/A

2

Description
Intervention group1: in headphone group (without playing any sounds) besides receiving Indomethacin suppository no sound would be played and then pain score and Hemodynamic signs would be measured and recorded in the abovementioned times.
Category

Treatment - Other

3

Description
Intervention group 2: The third group which is intervention group using headphone and playing sounds would receive mild nature sounds such as birds, rivers, waterfalls sounds for each individual patient and the pain score would be recorded.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahhari Hospital
Full name of responsible person
Farzaneh Mehran
Street address
Motahhari Blvd, Jahrom
City
Jahrom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Jahrom University of Medical Sciences
Full name of responsible person
Solh Ju Kavos
Street address
Vice chancellor for research, Jahrom University of Medical Sciences, Motahhari Blvd, Jahrom
City
Jahrom
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, Jahrom 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
Jahrom University of Medical Sciences
Full name of responsible person
Farzaneh Mehran
Position
Anesthesia Undergraduate Student
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Abbasi Jahromi Ali
Position
Faculty member
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Jahrom University of Medical Sciences
Full name of responsible person
Farzaneh Mehran
Position
Anesthesia Undergraduate Student
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