

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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

Street address

Nursing and Midwifery College, Motahhari Blvd, Jahrom

City

Jahrom

Postal code

Phone

+98 71 3743 8517

Fax

Email

MehranFarzaneh711@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Abbasi Jahromi Ali

Position

Faculty member

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Motahhari Blvd, Jahrom

City

Jahrom

Postal code

Phone

+98 71564742546

Fax

Email

Abbasija@jums.ac.ir

Web page address

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

Street address

Nursing and Midwifery College, Motahhari Blvd, Jahrom

City

Jahrom

Postal code

Phone

+98 71 3743 8517

Fax

Email

MehranFarzaneh711@gmail.com

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