

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical trials of checking the effect of music therapy during cesarean section on serum β endorphin, Vital Sign and postoperative pain on pregnant women

Protocol summary

Summary

The aim of this study is to find a nonpharmacological or behavioral method for pain relief which leads to a progress in recovery specially after a cesarean section that needs rapid contact of mother and baby. In this intervention clinical trial research which doesn't contain a placebo, patients undergoing a cesarean section at Al Zahra Hospital who meet the inclusion criteria, are randomly studied. Sampling in this research is systematic and the number of subjects, based on previous similar studies and sample size formula, is 41 patients in each group. Sample assignment to music therapy group and non music therapy control is based on the table of random numbers; which is classified in phase 2 of researches. Before beginning of the study in maternity ward, the intervention procedure is defined for patients, informed consent form of the research is filled by them. Inclusion criteria includes: cesarean section on primipara women with obstetrics and gynecology indication. In the event of any complications, if the patient is not interested in music or withdraws, the sample is eliminated from the study. For music therapy, an MP3 player and a headphone set is used which plays light instrumental or religious music. The music is played from the first moment of beginning of operations and takes 30 minutes. Then its effect on serum β endorphin, Vital Signs and postoperative pain will be studied.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041216325N5**

Registration date: **2017-07-28, 1396/05/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-28, 1396/05/06

Registrant information

Name

Katayoun Haryalchi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 5624

Email address

haryalchi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Guilan University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trials of checking the effect of music therapy during cesarean section on serum β endorphin, Vital Sign and postoperative pain on pregnant women

Public title

The effect of music therapy on pain of cesarean section

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: 1. Cesarean section on primipara women 2. Obstetrics and gynecology indications for cesarean section 3. Spinal anesthesia Exclusion criteria: 1. History of laparotomy 2. Physical and mental illnesses 3. Chronic pains 4. Occurrence of any complications during operations and anesthesia 5. In the event that patients are not interested in the music 6. If the patients ask for stopping music therapy during the operation 7. Patients' withdraw

Age

From **20 years** old to **30 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Sampling in this research is systematic and the number of subjects, based on previous similar studies and sample size formula, is 41 patients in each group. Sample assignment to music therapy group and non music therapy control is based on the table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Gaz square

City

Rasht

Postal code

Approval date

2017-02-25, 1395/12/07

Ethics committee reference number

IR.GUMS.REC.1395.362

Health conditions studied

1

Description of health condition studied

Single spontaneous delivery

ICD-10 code

O82

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

β endorphin

Timepoint

Before and after operation

Method of measurement

ELISA kit

Secondary outcomes

1

Description

The pain

Timepoint

Immediately after the operation; 1 hour after the operation; 6 hours after the operation; 12 hours after the operation; 24 hours after the operation

Method of measurement

NRS scale

2

Description

Vital signs

Timepoint

Before the operation; immediately after the operation; 1 hour after the operation; 6 hours after the operation; 12 hours after the operation; 24 hours after the operation

Method of measurement

Heart rate per minute, blood pressure per millimeter Hg, respiratory rate in one minute, via manometer and pulse oximeter

3

Description

Used opioid

Timepoint

During the operation; immediately after the operation; 1 hour after the operation; 6 hours after the operation; 12 hours after the operation; 24 hours after the operation

Method of measurement

The amount of opioid drugs used for relieving pain in cc

Intervention groups

1

Description

In order to do music therapy we use a pair of headphones and an MP3 player which plays which plays light instrumental music from standard tracks, accepted by Psychiatric Association, or religious music. Playing music start at the beginning of operation and lasts for 30 minutes.

Category

Treatment - Other

2

Description

Non music therapy control group do not get any music therapy.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Reproductive health research center, Al Zahra hospital

Full name of responsible person

Dr. Katayoon Haryalchi

Street address

Namju street

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Guilan University of Medical sciences

Full name of responsible person

Dr Shadman Nemati

Street address

Gaz Squire

City

Rasht

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 of Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Samere Rasuli

Position

Bachelor student of surgical technology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Katayoon Haryalchi

Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Arezoo Arya

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Anesthesia student

Other areas of specialty/work

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Fax

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ArezooArya0@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