Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of TENS and music therapy on pain relief in labor and postpartum: A randomized clinical trial

Protocol summary

Study aim
Comparison of the effect of TENS and music therapy on pain relief in labor and postpartum

Design
A randomized control trial, community base with 3 groups of TENS(n=50) , music (n=50) and control (n=50), not blinded.

Settings and conduct
women with singleton pregnancy who reffer to Shohada hospital with inclusion criteria would enter to this study. At first the score of pain with VAS ruler will determine. Then women in music group(n=50) will listen to their favorite music during labor until 4 hours after delivery. TENS electrodes will be sticked to lumbar region(T10 - S2) of women in TENS group(n=50) during labor till 4 hours after delivery. Women in control group receive routine care(n=50). Every one hour during labor and every 2 hours during 4 hours after delivery and every 6 hours till 24 hours after delivery, women will be asked about the score of pain according to VAS ruler. In addition length of active phase, stage II of labor, maternal and neonatal complications, neonatal APGAR score, score of pain after delivery, analgesic usage during 24 hours after delivery and patients satisfaction will check and analyze with SPSS 21.

Participants/Inclusion and exclusion criteria
main inclusion criteria:women with singleton pregnancy which begins spontaneous labor pain and they are in the active phase of labor main exclusion criteria: patient unwillingness of cooperation in the study, indication for augmentation or cesarean section

Intervention groups
TENS(transcutaneous electrical nerve stimulation) group: patients who use TENS during active phase. Music group: patients who listen to their favorite music during active phase of labor. Control group: patients who use nothing during active phase.

Main outcome variables
pain score during labor and postpartum; duration of active phase and stage2 of labor, patient satisfaction, analgesic use, APGAR and umbilical cord PH.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160722029027N5**
Registration date: **2018-05-04, 1397/02/14**
Registration timing: **retrospective**

Last update: **2018-05-04, 1397/02/14**
Update count: **0**

Registration date
2018-05-04, 1397/02/14

Registrant information

Name
Leila Nazari

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 2271 8000

Email address
nazari@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-09-21, 1395/06/31

Expected recruitment end date
2018-03-20, 1396/12/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of TENS and music therapy on pain relief in labor and postpartum: A randomized clinical trial

Public title

Comparison of the effect of TENS and music therapy on pain relief in labor and postpartum: A randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

singleton pregnancy estimated fetal weight 2500-4000 cephalic presentation normal FHR no use of analgesic and opium from 48h before entrance into trial spontaneous labor pain normal back skin no history of cesarean section no contraindication of NVD no history of cardiorespiratory disease no history of psychology disorders no history of hearing disorders active phase of labor

Exclusion criteria:

patient unwillingness to continue cooperation indications for augmentation during labor indications for emergent C/S

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Actual sample size reached: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study,the patients will randomly and with random number tables and computerized, divided in 3 groups; TENS, music and control after initiation of active phase of labor

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University

Street address

Shahid chamran highway, Evin, next to Taleghani hospital

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2015-10-12, 1394/07/20

Ethics committee reference number

IR.SBMU.SM.REC.1394.48

Health conditions studied

1

Description of health condition studied

delivery

ICD-10 code

O80

ICD-10 code description

Single spontaneous delivery

Primary outcomes

1

Description

Pain score during labor

Timepoint

Before intervention, every 1 hour during active phase of labor till delivery

Method of measurement

visual analogue scale for measurement of pain with questionnaire

2

Description

Pain score in postpartum

Timepoint

Every 2 hours till 4 hours after delivery and every 6 hours till 24 hours after delivery.

Method of measurement

visual analogue scale for measurement of pain with questionnaire

Secondary outcomes

1

Description

Satisfaction

Timepoint

24 hours after delivery

Method of measurement

questionnaire

2

Description

duration of active phase

Timepoint

From entrance to active phase till full dilatation of cervix

Method of measurement

hour

3

Description

duration of stage 2 labor

Timepoint

From full cervical dilatation till delivery

Method of measurement

minuets

4

Description

neonatal APGAR

Timepoint

1 and 5 minutes after birth

Method of measurement

APGAR scoring system

5

Description

Analgesic usage in postpartum

Timepoint

24 hours after delivery

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group 1(TENS:trans cutaneous electrical nerve stimulation): TENS electrodes will stick to lumbar region of patients in this group from T10 to S2, from entrance of active phase till 4 hours after delivery. Electrical impulses are under control of the patient.

Category

Treatment - Devices

2

Description

Intervention group 2(music group): patients in this group will listen to their favorite musics from entrance to the active phase till 4 hours after delivery.

Category

Treatment - Other

3

Description

Control group: patients who enter to active phase of labor which receive routine care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tajrish shohada's hospital

Full name of responsible person

Dr. Leila Nazari

Street address

Tajrish square

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1989934148

Phone

+98 21 25719

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nazari@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences, Yaman st, Velenjak, Chamran highway

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1985717434

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zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Athena Behforouz

Position

Obstetric and Gynecology resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Tajrish square, Shohada's hospital

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behforouz.a@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

leila nazari

Position

Fellowship of Infertility

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Athena Behforouz

Position

Obstetric and Gynecology resident

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

IPD collected for the primary outcome measure will be shared

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

increasing the clinical information and for review articles

From where data/document is obtainable

Via email: behforouz.a@gmail.com

What processes are involved for a request to access data/document

Access will be done with the opinion of the professors involved in the work

Comments