

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison the effect of Music therapy and Entonox inhalation for pain relief in labor in pregnant women refer to the Shohada Tajrish hospital

Protocol summary

Summary

This randomized clinical trial is conducted to evaluate whether use of music or entonox gas could reduce labor pain. Between 2012 and 2013, a total of 150 women at 37 weeks or greater with spontaneous labor that have not conterandication of vaginal delivery are randomized to music, entonox gas and control groups. Fast music without words is played for M group. The mask of entonox is provided for E group. Routine cares are used for all groups. Labor pain was assessed on a visual analogue scale (VAS) at beginning of the active phase and then every 1 hour. Duration of active phase of labor will record.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206198151N2**
Registration date: **2012-11-15, 1391/08/25**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-15, 1391/08/25

Registrant information

Name

Ladan Ajori

Name of organization / entity

Shahid beheshti university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2218 1694

Email address

ajori@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Science

Expected recruitment start date

2012-05-04, 1391/02/15

Expected recruitment end date

2013-05-05, 1392/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Music therapy and Entonox inhalation for pain relief in labor in pregnant women refer to the Shohada Tajrish hospital

Public title

Music therapy or Entonox inhalation for pain relief in labor : a randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria are: gestational age between 37 and 42 weeks; singelton pregnancy ;estimated fetal weight between 2500 and 4000 gram; normal fetal heart rate; cephalic presentation; spontaneous onset of labor. The exclusion criteria are: using analgesics and opium within 48 hours before admission; previous cesarean section; conterandications of vaginal delivery; indications of induction or stimulation of labor; pulmonary or heart diseases; psychological disorders; hearing loss and indications of emergency termination of pregnancy.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Beheshti University of Medical Science

Street address
Chamran Highway, Yaman Street

City
Tehran

Postal code

Approval date
2012-04-18, 1391/01/30

Ethics committee reference number
91-9780

Health conditions studied

1

Description of health condition studied
pain and duration of labor

ICD-10 code
O63

ICD-10 code description
long labour

Primary outcomes

1

Description
labor pain

Timepoint
at the beginning of active phase and then every 1 hour

Method of measurement
VAS Score

2

Description
duration of active phase

Timepoint
from beginning of active phase of labor to full dilatation of cervix

Method of measurement
minutes

Secondary outcomes

1

Description
maternal complications

Timepoint
at the end of the study

Method of measurement
history and physical examination

2

Description
fetal complications

Timepoint
at the end of the study

Method of measurement
physical examination

3

Description
cesarean rate

Timepoint
at the end of study

Method of measurement
hospital documents

4

Description
neonatal Apgar

Timepoint
first and fifth minutes

Method of measurement
Apgar score

Intervention groups

1

Description
entonox gas, in active phase of labor with uterin contractions

Category
Treatment - Drugs

2

Description
fast music therapy, in active phase of labor

Category

Treatment - Other

3

Description

standard cares

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada hospital

Full name of responsible person

Leila Nazari

Street address

Tajrish square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Science

Full name of responsible person

Seyyed Jalaeddin Khoshnevis

Street address

Tajrish hospital

City

Tehran

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 Science

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

Shahid Beheshti University of Medical Science

Full name of responsible person

Leila Nazari

Position

Gynecologist

Other areas of specialty/work

Street address

Shohada hospital

City

Tehran

Postal code

Phone

+98 21 2271 8006

Fax

Email

leynaz@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Science

Full name of responsible person

Ladan Ajori

Position

Gynecologist, Assistant Professor

Other areas of specialty/work

Street address

Shohada hospital

City

Tehran

Postal code

Phone

+98 21 2271 8008

Fax

Email

ajori@sbmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Science

Full name of responsible person

Leila Nazari

Position

Gynecologist

Other areas of specialty/work

Street address

Shohada hospital

City

Tehran

Postal code

Phone

+98 21 2271 8005

Fax

Email

leynaz@yahoo.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