

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the effects of Entonox and Transcutaneous Nerve Stimulation in labor pain

Protocol summary

Summary

One of the most important challenges in medicine is decreasing the labor pain. Many different methods have been used including applying Transcutaneous Nerve Stimulation (TENS) and inhalation of Entonox during labor. However the results are inconsistent. General objective of this study is determining the efficacy of TENS & ENTONOX in decreasing the labor pain. Specific objectives include comparison of the duration of first stage of labor in 3 groups, determining the trend of pain appearing in different dilatations in 3 groups, comparison of pain intensities in different dilatations in 3 groups, comparison of the amount of analgesics used, nausea & vomiting and apgar of newborn in 3 groups. Inclusion criteria are: Normal monofetus term pregnancy (37-42 weeks), Normal vaginal delivery, lack of request for epidural anesthesia, head down position of the fetus, uncomplicated pregnancy, less than 4 cm cervix dilatation, age of mother between 20-40 years & satisfying of mother regarding awareness of the methods used in the study. Exclusion criteria: Multifetus pregnancy, Hx of D.M, Hypertension, dermal skin infections, cardiovascular diseases, pacemaker, coagulation disorders or other diseases of the mother and preterm delivery. Sampling will be done by simple accessibility & the patients will be divided in 3 groups of TENS, Entonox and mixed group by random. Total numbers of patients are 117 with 39 patients in each group. Type of study is clinical trial. Analysis of the quality data will be done by descriptive statistical methods of X² and of the quantity ones by ANOVA methods. Study will performed in Emamreza & Motazedi hospitals by gynecologic residents who assist in performing the medical examination and obtaining written consent from the patients. Our intervention will be done just in the first stage of delivery (dilatation of cervix 4-10 cm). VAS will be used for evaluation of pain intensity in the form of 10 cm ruler. Methodolgy in TENS group comprises putting pad electrodes on T10-L1 & S2-

S4 spinal levels, then the patient could turn on the TENS device by when uterus contractions begin & turn it off when it end. She could change the frequency of impulses at pleasure. Inhalation of Oxygen will be used as a Entonox placebo. Patients in the Entonox group compress the button on the mask to inhale Entonox by start of the contractions & end it by releasing the button. Silent TENS will be used as a placebo in this group. In third group both TENS & Entonox will be used simultaneously. Main outcome measures include: Duration of first stage of delivery, pain intensity, use of analgesics, nausea & vomiting & apgar of newborn

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011295274N1**

Registration date: **2010-12-29, 1389/10/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-12-29, 1389/10/08

Registrant information

Name

Soheila Samadzadeh

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1839 1549

Email address

s_samadzadeh@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2010-12-06, 1389/09/15

Expected recruitment end date

2012-01-25, 1390/11/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Entonox and Transcutaneous Nerve Stimulation in labor pain

Public title

Comparison of the effects of Entonox and Transcutaneous Nerve Stimulation in labor pain

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: Normal monofetus term pregnancy(37-42 weeks) , normal vaginal delivery , lack of request for epidural anesthesia, head down position of fetus , uncomplicated pregnancy , less than 4 cm of cervix dilatation, age of mother between 20-40 years and satisfying of mother regarding awareness of the methods used in the study . Exclusion criteria: Multifetus pregnancy , history of diabetic mellitus , hypertension, dermal skin infections such as herpes zoster , epilepsy , cardiovascular diseases, pacemaker , coagulation disorders or other diseases of the mother , preterm delivery

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **117**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees

1

Ethics committee**Name of ethics committee**

Ethical committee of clinical developmental research of Emamreza hospital

Street address

ZekariayehraziBV Emamreza hospital

City

kermanshah

Postal code**Approval date**

2010-06-13, 1389/03/23

Ethics committee reference number

2983

Health conditions studied

1

Description of health condition studied

labor pain

ICD-10 code

080-084

ICD-10 code description

Primary outcomes

1

Description

pain intensity

Timepoint

4 times: before intervention , at the dilatation of 4-6 - , 6-8 and 8-10 cm

Method of measurement

visual analogue scale

Secondary outcomes

1

Description

duration of first phase of delivery

Timepoint

dilatation of 4-10 cm

Method of measurement

vaginal examination regarding time measuring

2

Description

Nausea & vomiting

Timepoint

During labor and till 24 hours after delivery

Method of measurement

Inspection or asking the patient

3

Description

Apgar of newborn

Timepoint

Immediately after delivery

Method of measurement

by recording scores

4

Description

Use of analgesics

Timepoint

During labor

Method of measurement

Patient notes

Intervention groups

1

Description

GROUP1: This group use the TENS device , which it,s electrodes put on the spine at the level of T10-L1 & S2-S4 . The patient turn on the device by beginning the uterus contractions & can change it,s frequencies. She turns off the device by compressing the power key as contractions cease. Oxygen inhalation is used as a placebo in this group.

Category

Prevention

2

Description

Group 2- In this group the patient press a button on the mask to inhale Entonox while uterus contractions begin . She ends the inhalation by ceasing the contractions . Silent TENS is used in this group as a placebo.

Category

Prevention

3

Description

Group 3- In this group the patients use both TENS & Entonox simultaneously

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Research center of high risk pregnancies -Emamreza hospital

Full name of responsible person

Dr. Negin Rezavand, Gynecologist

Street address

Zekariayeyrazi BV. Emamreza hospital

City

Kermanshah

2

Recruitment center

Name of recruitment center

Motazedi hospital

Full name of responsible person

Dr. Hanieh Feizmahdavi

Street address

Ferdosi street

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research , Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Shahid Beheshti Bv , number 2 building , Kermanshah university of Medical Sciences

City

kermanshah

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 , Kermanshah 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

Farabi Hospital Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Soheila Samadzadeh , physiatrist

Position

Assistant Professor

Other areas of specialty/work

Street address

Ashayer Bv , Farabi Hospital

City

Kermanshah

Postal code

Phone

+98 83 1826 0700

Fax

Email

s_samadzadeh2000@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Farabi hospital , kermanshah University of Medical sciences

Full name of responsible person

Dr. Soheila Samadzadeh

Position

assistant proffesor

Other areas of specialty/work

Street address

Ashayer Bv Farabi hospital

City

Kermanshah

Postal code

Phone

+98 83 1826 0700

Fax

Email

s_samadzadeh2000@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Farabi hospital ,Kermanshah University of Medical Sciences

Full name of responsible person

Dr. soheila samadzadeh

Position

Assistant professor , Physiatrist

Other areas of specialty/work

Street address

ashayer Bv Farabi hospital

City

kermanshah

Postal code

Phone

+98 83 1826 0700

Fax

Email

s_samadzadeh2000@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