Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 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 epidoral 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

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Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research , Kermanshah University of Medical Sciences

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 epidoral 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
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Kermanshah

2

Recruitment center
Name of recruitment center
Motazedi hospital
Full name of responsible person
Dr. Hanieh Feizmahdavi
Street address
Ferdosi street
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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
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Dr. Soheila Samadzadeh , physiatrist
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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