Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

Comparition effect of transcutaneous electrical nerve stimulation and epidural analgesia with lidocaine 1% on pain and prognosis of labour

Protocol summary

Summary

We decided to compare Epidural &TENS effects on progress and labour pain . In this single blind study 105 parturients aged 20-40 years for vaginal delivery in Fatemy hospital in Hamadan in 2014-2015 after informed consent randomly (five person block)assigned to three groups (No=35).In Epidural group ,Epidural catheter is placed in active phase of labour (cervical dilation=5cm) and 10 ml lidocaine %1plus 1ml sufentanil is injected. In secondary stage, 15 ml lidocaine %1is injected by epidural catheter. In TENS group two pairs electrodes are placed in T0-L1&S2-S4 nerve roots. In first and second stages of labour electrodes connected to TENS device and set by 10-18 MA stimulation and 100 HZ frequency for 30 minutes .In control group, any methods is used but TENS electrodes are placed .In three groups vital signs and vas of labour pain in 5,10,15 &30 minutes after analgesia ,second stage of labour and after delivery are measured. Duration of first and secondary stage of labour ، nausea and vomiting ,itching, respiratory depression ,request to cesarean section ,patient satisfaction and neonatal apgar score are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071610841N5**
Registration date: **2016-04-23, 1395/02/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-04-23, 1395/02/04

Registrant information

Name

Nahid Manuchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Hamadan University Of Medical Science

Expected recruitment start date

2014-07-02, 1393/04/11

Expected recruitment end date

2016-03-30, 1395/01/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparition effect of transcutaneous electrical nerve stimulation and epidural analgesia with lidocaine 1% on pain and prognosis of labour

Public title

Comparition of transcutaneous electrical nerve stimulation and epidural analgesia in labour pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Voluntarily participate in research; candidate for vaginal delivery; fetus cephalic presentation;term pregnancy;uncomplicated pregnancy;patients in active phase with >5cm dilation of

cervix Exclusion criteria: Cutaneous infection in back region (urticaria, insects and scar); previous cesarean section; patients with pacemaker;contraindications of epidural analgesia(couagolopathy ,hypovolemia,region cutaneous infection,increasing ICP and anemia)

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

Gender
Female

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **105**

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
Ethics Committee of Hamadan university of Medical Science

Street address
Fahmide Street

City
Hamadan

Postal code
6517838678

Approval date
2014-06-08, 1393/03/18

Ethics committee reference number
پ/د/712/16/35/9

Health conditions studied

1

Description of health condition studied
delivery

ICD-10 code
080.0

ICD-10 code description
Spontaneous vertex delivery

Primary outcomes

1

Description
labour pain

Timepoint
5-10-15 and30 minutes after analgesia

Method of measurement
visual analgesic scale

2

Description
labour progress

Timepoint
labour duration

Method of measurement
duration of first and second stages of labour

3

Description
Heart Rate

Timepoint
5-10-15 and30 minutes after analgesia

Method of measurement
nomber of heart rate per minute

4

Description
systolic and diastolic blood presure

Timepoint
5-10-15 and30 minutes after analgesia

Method of measurement
non invasive bloon presure monitoring

5

Description
Tempreture

Timepoint
5-10-15 and30 minutes after analgesia

Method of measurement
Termometer

6

Description
new born Apgar

Timepoint
1&5 minutes after delivery

Method of measurement
Apgar Score

7

Description
Satisfactory

Timepoint
After delivery

Method of measurement

questioning

8

Description
Cesarean Section
Timepoint
Duration of labour
Method of measurement
Observation

Secondary outcomes

1

Description
Nausea & vomiting
Timepoint
during &after delivery
Method of measurement
Observation

2

Description
Itching
Timepoint
during &after delivery
Method of measurement
Observation &visual scale

3

Description
Respiratory Depression
Timepoint
during &after delivery
Method of measurement
Respiratory rate & Spo2

Intervention groups

1

Description
In Epidural group ,Epidural catheter is placed in active phase of labour(cervical dilation=5cm) and 10 ml lidocaine %1plus 1ml sufentanil is injected.In secondary stage,maximum 15 ml lidocaine %1is injected by epidural catheter.
Category
Prevention

2

Description
In TENS group two pairs electrodes are placed in T0-L1&S2-S4 nerve roots. In first and second stages of labour electrodes connected to TENS device and set by 10-18 MA stimulation and 100 HZ frequency for 30 minutes .
Category
Prevention

3

Description
In control group, any methods of analgesia is used but TENS electrodes are placed .
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Nahid Manouchehrian
Street address
Pasdaran Street
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research Hamadan University Of Medical Science
Full name of responsible person
Dr. saeed Bashirian
Street address
Fahmide Street
City
Hamadan
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 Hamadan 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

Hamadan University of Medical Science-Fatemie Hospital

Full name of responsible person

Dr. Nahid Manouchehrian

Position

associated professor of anesthesia Department

Other areas of specialty/work

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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