Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of effects of transcutaneous electrical nerve stimulation and of pharmaceutical hyoscine– promethazine compound on duration of the second phase of labor

Protocol summary

Summary

This research is a randomly clinical 2-group ergometric one done in order to compare effects of TENS with those of hyoscine-promethazine compound on duration of the second stage of labor. At the onset of active labor phase (4-cm dilatation), medication group subject were injected once intramuscularly by 20 mg of hyoscine and 25 mg of promethazine simultaneously. For TENS group, was used with 1 pair of upper electrodes placed between L1-T10 and 1 pair of lower electrodes placed between S2-S4 apart 7 cm from both side of spinal column. Tens being on/off for 20 min/20 min until the second phase of labor(10cm dilatation) completed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604144317N10**
Registration date: **2017-03-14, 1395/12/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-03-14, 1395/12/24

Registrant information

Name

Fatemeh Nahidi

Name of organization / entity

Shahid Beheshti University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 982188202512

Email address

nahidi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

private

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effects of transcutaneous electrical nerve stimulation and of pharmaceutical hyoscine–promethazine compound on duration of the second phase of labor

Public title

delivery

Purpose

Treatment

Inclusion/Exclusion criteria

1. Being of Iranian race; 2. The first and /or the second labor; 3. Being 18-35 years of old; 4. Term pregnancy, single-twin, and presentation of fetus head; 5. Onset of spontaneous contractions; 6. Dilatation examination upon arrival at 3-4 cm; 7. Minimum education level of elementary grade 5; 8. Not taking painkillers 3 hours before and during study; 9. Mot more than 6 hours passed after caul rupture; 10. Lack of experience with TENS; 11. No epilepsy; 12. No cardiac pacemakers; 13. No use of substance/ drugs; and 14. No skin lesions or

surgical scars at the place of electrodes. And followings are criteria for women ti be excluded from the study; 1. Emergency caesarean prior to the study completion; research; 2. Occurrence of such labor complications as vaginal bleeding during research; 3. Patients reluctance to continue participating in the study; and 4. Wounds or scars present at the place of electrodes.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **84**

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 sciences

Street address
tehran

City
tehran

Postal code

Approval date
2015-07-28, 1394/05/06

Ethics committee reference number
ir.sbmu.phnm.1394.43

Health conditions studied

1

Description of health condition studied
delivery

ICD-10 code
xv

ICD-10 code description
Pregnancy, childbirth and the puerperium

Primary outcomes

1

Description
pain intensity

Timepoint
At 4-5 cm, 6-7 cm, 8-9cm, 10cm

Method of measurement
pain visual scale

Secondary outcomes

1

Description
duration of the first phase of labor

Timepoint
duration of the first phase((upon arrived until 10-cm dilatation)

Method of measurement
wristwatch

2

Description
duration of the second phase of labor

Timepoint
second phase (from 10-cm dilatation to the fetus exit)

Method of measurement
wristwatch

Intervention groups

1

Description
At the onset of active labor phase (4-cm dilatation), medication group subject were injected once intramuscularly by 20 mg of hyoscine and 25 mg of promethazine simultaneously.

Category
Treatment - Drugs

2

Description
For TENS group, was used with 1 pair of upper electrodes placed between L1-T10 and 1 pair of lower electrodes placed between S2-S4 apart 7 cm from both side of spinal column. Tens being on/off for 20 min/20 min until the second phase of labor(10cm dilatation) completed.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Martyr Chamran Hospital of Kangavar

Full name of responsible person
Massumeh Payandeh
Street address
City
Kangavar

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
shahid beheshti university of medical sciences
Full name of responsible person
Massumeh Payandeh
Street address
tehran
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 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
shahid beheshti university of medical sciences
Full name of responsible person
fateme nahidi
Position
phd
Other areas of specialty/work
Street address
faculty nursing & midwifery
City
tehran
Postal code
Phone
+218 8202512
Fax
Email
nahidi@sbmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
shahid beheshti university of medical sciences
Full name of responsible person
Masumeh Payandeh
Position
master of midvifery
Other areas of specialty/work
Street address
tehran
City
tehran
Postal code
Phone
+218 8202512
Fax
Email
m_paiande@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
Masumeh Payandeh
Position
Other areas of specialty/work
Street address
City
Postal code
Phone
008348238714
Fax
Email
m_paiande@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