

# 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. Not 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 to 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.sbm.u.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 &amp; midwifery

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nahidi@sbmu.ac.ir

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shahid beheshti university of medical sciences

**Full name of responsible person**

Masumeh Payandeh

**Position**

master of midwifery

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Masumeh Payandeh

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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*