

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of the effect of transcutaneous electrical nerve stimulation (TENS) with the injection of pethidine and promethazine in labor pain reduction

Protocol summary

Study aim

Comparison of the effect of transcutaneous electrical nerve stimulation (TENS) with the injection of pethidine and promethazine in labor pain reduction

Design

This three-phase clinical trial, with parallel groups, randomized (using the random allocation rule) is performed on 90 pregnant women.

Settings and conduct

This randomized clinical trial study is performed on 90 pregnant women, in Yas Hospital. The sampling method is a convenience method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with 16 to 40 years and term pregnancy (gestational age: 37 to 41 weeks), Singleton pregnancy, Cephalic presentation, Spontaneous vaginal delivery Criteria for not entering: Preeclampsia, Gestational diabetes with insulin therapy, Intrauterine growth restriction, History of C/section, Meconium in amniotic fluid, History of transmural myomectomy or uterus rupture

Intervention groups

In the active phase of labor (cervical dilation: 4 cm with uterine contractions), in the first group of intervention, 100 milligrams of pethidine and 250 micrograms of promethazine will be injected intramuscular, if the pregnant women will not respond to the primary dose, the second dose will be applied. In the second group of intervention, TENS continuously for 120 minutes will be applied.

Main outcome variables

The labor pain will be measured before the intervention and half time after the intervention by Visual Analogue Scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190208042655N1**

Registration date: **2021-05-11, 1400/02/21**

Registration timing: **prospective**

Last update: **2021-05-11, 1400/02/21**

Update count: **0**

Registration date

2021-05-11, 1400/02/21

Registrant information

Name

Nafiseh Saedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2298 0727

Email address

nsaedi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-31, 1400/03/10

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of transcutaneous electrical nerve stimulation (TENS) with the injection of pethidine and promethazine in labor pain reduction

Public title

Comparison of the effect of TENS with the injection of pethidine and promethazine in labor pain reduction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women 16 to 40 years and term pregnancy (gestational age: 37 to 41 weeks) Singleton pregnancy Cephalic presentation Spontaneous vaginal delivery

Exclusion criteria:

Preeclampsia Gestational diabetes with insulin therapy Intrauterine growth restriction History of C/section Meconium in amniotic fluid History of transmurial myomectomy History of uterus rupture

Age

From **16 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation rule: First, 45 letters A and 45 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patient. In addition, interventions A or B are determined by a lot.

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

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, School of Medicine, Tehran Province, Tehran, Pour Sina St" to "Tehran University of Medical Sciences, School of Medicine, Tehran Province, Tehran, Pour Sina St

City

Tehran

Province

Tehran

Postal code

1598718311

Approval date

2019-04-15, 1398/01/26

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.013

Health conditions studied

1

Description of health condition studied

Painless delivery

ICD-10 code

F45.41

ICD-10 code description

Pain disorder exclusively related to psychological factors

Primary outcomes

1

Description

The labor pain

Timepoint

Before the intervention and half time after the intervention

Method of measurement

By Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the active phase of labor (cervical dilation: 4 cm with uterine contractions), in the first group of intervention, 100 milligrams of pethidine and 250 micrograms of promethazine will be injected intramuscular, if the pregnant women will not respond to the primary dose, the second dose will be applied.

Category

Treatment - Drugs

2

Description

Intervention group: In the active phase of labor (cervical dilation: 4 cm with uterine contractions), TENS

continuously for 120 minutes will be applied.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Nafiseh Saedi

Street address

Yas hospital, Next to the sarv street , North
Nejatollahi street , karim khan ave

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Postal code

1597856511

Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice-Dean of Research of Tehran University of Medical
Sciences, Dr. Sahraiyen

Street address

Vice-Dean of Research, Tehran University of Medical
Sciences, Floor 6, Qods St., Keshavarz Blvd, Tehran,
Iran

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1416634793

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+98 21 8163 3698

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vcr@tums.ac.ir

Grant name

Grant code / Reference number

**Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nafiseh Saedi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Tehran University of Medical Sciences

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentified participants

When the data will become available and for how long

After manuscript published

To whom data/document is available

No limitations

Under which criteria data/document could be used

The data is only available to the project manager, Dr. Saedi, and any analysis must be done with her opinion.

From where data/document is obtainable

Dr. Nafiseh Saedi

What processes are involved for a request to access data/document

Any request must be made in writing and accompanied by a proposal with an ethics code under the supervision of Dr. Nafiseh Saedi.

Comments