Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 transmural 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

City
Tehran

Province
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Postal code
1597856511

Phone
+98 21 8608 9089

Email
nsaedi@sina.tums.ac.ir

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. Sahraiyan

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

City
Tehran

Province
Tehran

Postal code
1416634793

Phone
+98 21 8163 3698

Email
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 updating data

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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