Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jul 2026

The effect of TENS on the severity of pain during medical abortion in the first trimester of pregnancy in comparison with the control group

Protocol summary

Study aim

1.Comparison of two groups for pain intensity at the time of starting use of TENS and at 2, 4, 6, 8 and 10 hours after using TENS and at the time of abortion 2. Comparison of two groups for satisfaction of the process of analgesia 3. Comparison of two groups for satisfaction of the process of abortion 4. Comparison of two groups for satisfaction of using of TENS 5. Comparison of two groups for medical abortion success 6. Comparison of two groups for side effects 7. Comparison of two groups for amount of ibuprofen consumption

Design

Clinical Trial, with two parallel groups, triple blind, randomized, phase 2 with 60 patients. The order of the patients was questioned from an external source who identified the sequence by the block randomized method.

Settings and conduct

Back ground: First trimester abortion, Taleghani and Akbar Abadi Hospitals, Clinical trial, Triple blind: Researcher, Analyzer, Patients

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with gestational age less than 13 weeks according to LMP and ultrasound who are candidate for medical abortion with misoprostol. Excluding criteria: Allergy to misoprostol and ibuprofen, Drug addiction, History of chronic pain, History of using TENS.

Intervention groups

Intervention group: Pregnant women candidate for pregnancy termination with misoprostol in the first trimester who take Ibuprofen and TENS for analgesia. Control group: Pregnant women candidate for pregnancy termination with misoprostol in the first trimester who take ibuprofen for analgesia.

Main outcome variables

Pain during hospitalization, pain when starting to use TENS, pain at 2, 4, 6, 8 and 10 hours after starting to use TENS Satisfaction of abortion process, satisfaction of analgesia, satisfaction of TENS, amount of Ibuprofen used, success of abortion, side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170515033989N2**
Registration date: **2021-11-17, 1400/08/26**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-17, 1400/08/26**
Update count: **0**

Registration date

2021-11-17, 1400/08/26

Registrant information

Name
Minoo Yaghmaei
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 2243 2590
Email address
m.yaghmaei@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-01, 1400/08/10

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of TENS on the severity of pain during medical abortion in the first trimester of pregnancy in comparison with the control group

Public title

The effect of TENS on the severity of pain during medical abortion pain in the first trimester of pregnancy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Single pregnancy Less than 13 weeks of pregnancy Body mass index below 30 kg / m2 Candidate for termination of pregnancy with Misoprostol

Exclusion criteria:

Sensitivity to Misoprostol and Ibuprofen Drug addiction History of chronic pain History of using TENS

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of block: There will be twelve blocks, each block containing 5 units. For randomization statistical software will be used and the result will provided to a person outside the research group. For each patient who meets the including, this person will be contacted and she will announce the group (control or case).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, TENS device is connected to both case and control groups, however, it is active in the case group and inactive in the control group. The person who fills in the questionnaire and records the outcomes, as well as the researcher who collects the information and the person who performs the analysis, are blind to the membership of participants.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Taleghani Hospital, Arabi st., Daneshjoo Blv, Shahriari sq., Evin

City

Tehran

Province

Tehran

Postal code

1985717418

Approval date

2021-09-18, 1400/06/27

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.266

Health conditions studied

1

Description of health condition studied

Medical Abortion

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Ibuprofen intake

Timepoint

Once at the end of the abortion process

Method of measurement

Dosage consumed throughout the abortion process (mg)

2

Description

pain

Timepoint

At the beginning of hospitalization - at the beginning of using TENS - at 2, 4, 6, 8 and 10 hours after TENS

Method of measurement

Numeral Visual scale (NVS)

3

Description

Satisfaction with the whole abortion process

Timepoint

Once the abortion process is completed

Method of measurement
Based on the question from the patient - bad - normal - good - excellent

4

Description
Satisfaction with the analgesia process
Timepoint
Once the abortion process is completed
Method of measurement
Based on the question from the patient - bad - normal - good - excellent

5

Description
Satisfaction with the use of the TENS device
Timepoint
Once the abortion process is completed
Method of measurement
Based on the question from the patient - bad - normal - good - excellent

6

Description
Duration of use of TENS
Timepoint
Once the abortion process is completed
Method of measurement
Minute

7

Description
Side effects
Timepoint
Once the abortion process is completed
Method of measurement
Question from the patient and examination and mention of the complication

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Using TENS and Ibuprofen to reduce pain in first trimester abortion candidates with misoprostol - Ibuprofen administration method: Ibuprofen Tab (produced by Loghman Pharmaceuticals) 200 mg (in case of moderate pain) or 400 mg (in case of severe pain). TENS (HMB-1000 TENS, South Korea) : Four pads are placed two in the lower abdomen and two in the waist area, which is connected to the device with a wire. TENS is set at a frequency of 80 Hz with an intensity of 0 to 80 (according to the patient's wishes).
Category
Treatment - Devices

2

Description
Control group: Use of unbound TENS (placebo) and ibuprofen to reduce pain in first trimester abortion candidates with misoprostol - Method of administration of ibuprofen tablet (produced by Loghman Pharmaceuticals) 200 mg (in case of moderate pain) or 400 mg (in case of Severe pain). In this group, four TENS pads (HM-1000, made in South Korea) are placed two in the lower abdomen and two in the waist area, but the connection wire between the pad and the device is not connected.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Minoo Yaghmaei
Street address
Taleghani Hospital, Erabi street, Daneshjoo Blv, Shahriari sq, Evin
City
Tehran
Province
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Postal code
1985717413
Phone
+98 21 2243 2560
Email
m.yaghmaei@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Vice President for Research and Technology
Street address
Taleghani Hospital, Erabi street, Daneshjoo Blv, Shahriari sq, Evin
City
Tehran
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1985717413
Phone
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Email

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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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Minoo Yaghmaei

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Minoo Yaghmaei

Position

Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Minoo Yaghmaei

Position

Professor

Latest degree

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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

Yes - There is a plan to make this available

Title and more details about the data/document

All data is available on demand after being unidentifiable

When the data will become available and for how long

Up to six months from the publication of the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Mention a valid request from the applicant

From where data/document is obtainable

Dr. Minoo Yaghmaei m.yaghmaei@sbmu.ac.ir

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

Must be emailed.

Comments