

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

EVALUATION OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION ON PAIN, SWELLING AND TRISMUS FOLLOWING THIRD MOLAR TOOTH EXTRACTION

Protocol summary

Evaluation of the efficacy of TENS in reduction the complications of impacted third molar surgery

Study aim

The effect of TENS on pain relief after latent third molar surgery Evaluation of the efficacy of TENS in reducing swelling after latent third molar surgery Evaluation of the efficacy of TENS in reducing trismus after latent third molar surgery

Design

The study is a double-blind randomized clinical trial with a control group. The sample size is 40 people. It has 2-3 trial phases. The study has two intervention and control groups, the first group receiving TENS at 50 Hz and the second group receiving 3 Hz (less than 10 Hz ineffective).

Settings and conduct

the study will be done in private office. The study will be designed as a double blind clinical trial using TENS with frequency of 50 Hz in the intervention group and 3 Hz in the control group. In group 1 patients will receive tens immediately after surgery in the angle and mandibular body region at 50 Hz and in group 2 (control group) the device will be administered at 3 Hz. The patient does not know which side of the TENS is used and which side of the placebo. patients and investigator are blind.

Participants/Inclusion and exclusion criteria

inclusion criteria patients who can participate in follow up sessions and filling the questionnaires and will be satisfied to be in the study exclusion criteria patients without any specific systemic disease.

Intervention groups

In group 1, patients receive tens immediately after surgery in the corneal area and mandibular body on the surgical side (Tens will be applied using the modern medical device company 620-p. 50 Hz frequency (short pulse for 100 micro Seconds) for 15 minutes daily for 6 days. In group 2 (control group), a device with a frequency of 3 Hz that has no effect will be prescribed.

Main outcome variables

General information

Reason for update

Acronym

TENS

IRCT registration information

IRCT registration number: **IRCT20191204045602N1**

Registration date: **2020-08-24, 1399/06/03**

Registration timing: **retrospective**

Last update: **2020-08-24, 1399/06/03**

Update count: **0**

Registration date

2020-08-24, 1399/06/03

Registrant information

Name

Aida Karagah

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-30, 1398/11/10

Expected recruitment end date

2020-04-29, 1399/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

EVALUATION OF TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION ON PAIN, SWELLING AND TRISMUS FOLLOWING THIRD MOLAR TOOTH EXTRACTION

Public title

Effect of electrical stimulation on pain, swelling and trisms of wisdom tooth

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

patients who can participate in follow up sessions and filling the questionnaires patients who were satisfied to be in the study patients without any specific systemic disease like; coagulation problems and diabetes, etc.

Exclusion criteria:

All patients with pathological lesions around the impacted jaw, restrict jaw movement and TMJ joint problems Patients taking sedatives Patients with a history of mandibular angle fracture smoker patients

Age

From **17 years** old to **30 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

In this study, one side of each patient will be randomly assigned to the TENS group (case) and the other to the placebo group (control).

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed using a sealed envelope with a computer-generated random allocation for each patient to determine the side on which TENS will be used. On the chosen side, tens will be used on patient and on the other side, tens won't be used. At the end, two sides will be comparisoned.

Blinding (investigator's opinion)

Double blinded

Blinding description

The extraction of third molar teeth under local anesthesia is done by a surgeon who is blind about case and control groups. A physician applies tens on each side. A third person, who is blind about whether the TENS is used, examines the patients pain, trismus, and dull.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of qazvin university of medical sciences

Street address

faculty of dentistry, qazvin university of medical science, bahonar blvd., qazvin

City

qazvin

Province

Qazvin

Postal code

3419915315

Approval date

2019-02-17, 1397/11/28

Ethics committee reference number

IR.QUMS.REC.1397.332

Health conditions studied**1****Description of health condition studied**

following pain of mandibular third molar tooth surgery

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

following trismus of mandibular third molar tooth surgery

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

following swelling of mandibular third molar tooth surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

quantity of post operative pain from 0 to 10

Timepoint

Recording the quantity of pain in 7 days during sleep by

the patient

Method of measurement

Visual Analogue Scale

2

Description

quantity of trismus after surgery

Timepoint

Recording the quantity of trismus before surgery and in second, fourth, seventh days after surgery

Method of measurement

evaluating intrajaw space's trismus with a ruler before and after surgery and reporting it based on centimeter

3

Description

post-operative swelling

Timepoint

evaluating swelling just after surgery and in second, fourth and seventh day after surgery

Method of measurement

measuring swelling with a ruler from tragus to lip commissure and the space between Gonion and lateral canthus and reported based on centimeter

Secondary outcomes

1

Description

the number of taken pain killers after surgery

Timepoint

number of taken pain killers in 7 days after surgery

Method of measurement

number of taken pain killers

Intervention groups

1

Description

Intervention group: TENS ,

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Private office

Full name of responsible person

aida karagah

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Leyli Shadman

Position

dental student

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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

No - There is not 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 documentation in CD format will be submitted to the university research unit at the end of the research.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

academic persons working in Qazvin university of medical sciences

Under which criteria data/document could be used

academic persons working in Iran and other countries

From where data/document is obtainable

email to investigator

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

email to investigator

Comments