Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

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

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

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)

Phone

+98 28 3333 8774

Email address

t.karagah@qums.ac.ir

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 truisms 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 intraincisal 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, forth and seventh day after surgery

Method of measurement

measuring swelling with a ruler from tragus to lip commisure and the space between Gonion and lateral canthus and reported based on centi meter

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

Street address

bahoonar blvd.

City

qazvin

Province

Qazvin

Postal code

3419915315

Phone

+98 28 3333 6001

Email

aida_karagah@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Aida Karagah

Street address

Qazvin University Of Medical Science, bahonar blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

3419915315

Phone

+98 28 3333 6001

Fax

+98 28 3335 5162

Email

Aida_karagah@yahoo.com

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

Dentistry
Street address
bahonaar blvd
City
qazvin
Province
Qazvin
Postal code
3419915315
Phone
+98 28 3333 6001
Email
leili_sh77@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
aida karagah
Position
assistant professor
Latest degree
Specialist
Other areas of specialty/work
oral and maxillofacial surgeon
Street address
bahounar blvd.
City
qazvin
Province
Qazvin
Postal code
3419915315
Phone
+98 28 3333 6001
Email
aida_karagah@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Azin Arjmand
Position
dental student
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Bahoonar blvd.
City
qazvin
Province
Qazvin
Postal code
3419915315
Phone
+98 28 3333 6001
Email
azin.arjmand@yahoo.com

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