

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The evaluation of effects of low-level laser on the healing of trismus, pain and swelling after mandibular impacted wisdom tooth extraction

Protocol summary

Study aim

Evaluation of the effect of low-level laser therapy on the healing time of trismus pain and swelling after impacted wisdom tooth extraction

Design

This study is a clinical trial study and one of the two mandibular wisdom teeth of the patient would be intervening and another side would be the control one. This study is single-blind because the patient does not know which side is intervening or control.

Settings and conduct

It would be done in the maxillofacial surgery department of the dental school of Shahid Beheshti University of medical science. Patients are going to be informed about the study plan before surgery. They get into the study just if they accept it. We start the measurements. One side would be the placebo and the other side would be the intervention. We put the laser device on both sides of the patients' mouth, turn it on, for the intervention side, and keep it off for the placebo side.

Participants/Inclusion and exclusion criteria

All patients who are aged between 18-30 years and have mandibular third molar symmetric impacted teeth are included in the study. Pregnancy; breastfeeding; smoking; any systemic or neurological disease; pericoronitis and laser therapy contraindications are not included in the study.

Intervention groups

In this study, a patient is in the intervening group in one side surgery and in the control group in the surgery of another side. The patient receives common medication in both surgeries. For intervention, we use low-level laser and LED on one side and the placebo on the other side as the control group.

Main outcome variables

We expect that this intervention affects the trismus, pain, and swelling after impacted mandibular wisdom tooth extraction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180608040005N1**

Registration date: **2020-05-04, 1399/02/15**

Registration timing: **retrospective**

Last update: **2020-05-04, 1399/02/15**

Update count: **0**

Registration date

2020-05-04, 1399/02/15

Registrant information

Name

Ghazale Keyvani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6635 0274

Email address

keyvani.ghazaleh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-15, 1398/03/25

Expected recruitment end date

2019-07-11, 1398/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The evaluation of effects of low-level laser on the healing of trismus, pain and swelling after mandibular impacted wisdom tooth extraction

Public title

The evaluation of effects of low-level laser on the healing of trismus, pain and swelling after mandibular impacted wisdom tooth extraction

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Whoever aged between 18-30 years old and has symmetric mandibular wisdom tooth which is candidate for surgical extraction

Exclusion criteria:

Not symmetric wisdom teeth Patient has any systemic or neurological disease Laser therapy contraindication Pulp involvement Smoking Pregnancy Breast feeding Pericoronitis

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

More than 1 sample in each individual

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

Both wisdom teeth

Randomization (investigator's opinion)

Randomized

Randomization description

Simple

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient does not know which side would be placebo or the laser.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Shahid Beheshti University Of
Medical Science

Street address

Dental School, Daneshjoo Blvd. Chamran Expy.
Tehran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2017-08-01, 1396/05/10

Ethics committee reference number

IR.SBMU.RIDS.REC.1396.502

Health conditions studied

1

Description of health condition studied

Pain, trismus and swelling after mandibular impacted wisdom tooth extraction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Trismus, pain and swelling would be measured before and after surgery

Timepoint

Before surgery, 3 days later, 7 days later

Method of measurement

For Pain the VAS system, for trismus a calipers, and a bending ruler for swelling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study the intervention is taking low-level laser right after surgery in 3 points. occlusal, buccal and one from out of the mouth, on the surgery spot.

Category

Treatment - Devices

2

Description

Control group: Patients take non-working Laser as placebo on the same three locations mentioned before

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School Of Shahid Beheshti University Of
Medical Science

Full name of responsible person

Ghazale Keyvani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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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

Ghazaleh Keyvani

Position

Dentistry student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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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

Yes - There is a plan to make this available

Title and more details about the data/document

The collected and measured data can be shared for
authorized executives and organizations

When the data will become available and for how long

One year after publication

To whom data/document is available

Data will be shared for people working in academic
institutions

Under which criteria data/document could be used

Using for academic studies

From where data/document is obtainable

By E-mail

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

After evaluating the reasons for asking for data, you will
be answered in one month

Comments