

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the Effectiveness of Red and Infrared Low level Laser Therapy for Post Operative Pain Control, Swelling and Trismus in Patients with Impacted Mandibular Third Molar

Protocol summary

Study aim

Evaluating the effectiveness of red and infrared low level laser therapy on pain control, swelling and trismus after impacted lower 3rd molar removal and comparing the amount of analgesic used in each group.

Design

Randomized double-blinded clinical trial with 3 parallel group design of 30 patients. Randomization is achieved through www.randomization.org website in 3 groups of 10 from number 1 to 30.

Settings and conduct

The study will be conducted in the department of Maxillofacial Surgery, Tabriz Faculty of Dentistry. In the first group red laser is applied extraorally on 2 occasions. In the second and the control group respectively infrared and placebo will be applied as described in the first group. Switching on /off of the laser therapy device is controlled by the responsible nurse and the patient and the researcher are blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients (aged 18 to 35) with impacted lower third molar without any systemic disease. Exclusion criteria: patients with distoangular or vertical impacted lower 3rd molar, soft tissue impaction, allergy to local anesthetics, systemic disease, local infection and pregnancy.

Intervention groups

In the first group red laser is applied extraorally on 2 occasions, before the impacted lower 3rd molar surgery and the other one is performed on the second day after operation. In the second group infra red laser is applied extraorally on 2 occasions, once before the impacted lower 3rd molar surgery and the other one is performed on the second day after operation. Placebo laser is applied extraorally on 2 occasions, once before the impacted lower 3rd molar surgery and the other one is performed on the second day after operation.

Main outcome variables

Variables include the severity of pain, swelling, trismus and the number of pain relief tablets taken.

General information

Reason for update

Acronym

LLLT

IRCT registration information

IRCT registration number: **IRCT20110420006239N2**

Registration date: **2019-06-07, 1398/03/17**

Registration timing: **registered_while_recruiting**

Last update: **2019-06-07, 1398/03/17**

Update count: **0**

Registration date

2019-06-07, 1398/03/17

Registrant information

Name

javad yezdani

Name of organization / entity

faculty of dentistry

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-06-10, 1398/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Red and Infrared Low level Laser Therapy for Post Operative Pain Control, Swelling and Trismus in Patients with Impacted Mandibular Third Molar

Public title

Evaluating the Effectiveness of Red and Infrared Low Level laser Therapy on Pain Control after Removal of Impacted Wisdom Teeth

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients admitted to the dental clinic who require the removal of impacted lower 3rd molar Patients who have impacted lower 3rd molar with grade IIIB or IIIC surgical difficulty according to Pell-Gregory classification Patients who have mesioangular impacted lower 3rd molar Patients without any systemic disease

Exclusion criteria:

Patients with distoangular or vertical impacted lower 3rd molar Soft tissue impaction of the lower 3rd molar Hypersensitivity to local anesthetics Patients with systemic disease Local infection Blood dyscrasias Patients with a history of gastric ulcer or patients who are currently suffering from a gastric ulcer Cardiovascular condition Pregnancy Lactation Patients who have used analgesic or anti inflammatory drugs 24 hours prior surgery Surgical procedures taking longer than 20 minutes

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is achieved through www.randomization.org website in 3 groups of 10 from number 1 to 30.

Blinding (investigator's opinion)

Double blinded

Blinding description

Switching on /off of the laser therapy device is controlled by the responsible nurse and the patient and the researcher are blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Dentistry faculty of Tabriz, Golgasht Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5166414766

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.TBZMED.REC.1397.1017

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

Trismus

ICD-10 code

R25.2

ICD-10 code description

Cramp and spasm

2**Description of health condition studied**

Pain

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

3**Description of health condition studied**

Swelling

ICD-10 code

R60

ICD-10 code description

Edema, not elsewhere classified

4

Description of health condition studied

Total analgesic drug consumption

ICD-10 code

Y45.3

ICD-10 code description

Other nonsteroidal anti-inflammatory drugs [NSAID]

Primary outcomes

1

Description

Pain

Timepoint

Day 2 post-operation, day 7 post-operation

Method of measurement

Visual analog scale (asking from patient, scoring from 1 to 10)

2

Description

Swelling

Timepoint

Pre-operation, day 2 post-operation, day 7 post-operation

Method of measurement

Measuring 3 parameters: 1-tragus-labial commissure distance, 2- Lateral canthus of eye-mandibular angle distance, 3-tragus-pogonion distance

3

Description

Trismus

Timepoint

Pre-operation, day 2 post-operation, day 7 post-operation

Method of measurement

Measuring the maximum space between central incisors of maxilla and mandible(in millimeter)

Secondary outcomes

1

Description

Number of pain relief tablets taken

Timepoint

Day 2 post-operation, day 7 post-operation

Method of measurement

Asking the patient

Intervention groups

1

Description

Intervention group:In first group red laser(with the wavelength of 660 nm and the power of 6 joules per square centimeter)is applied extraorally on 2 occasions, once 30 minutes before the impacted lower 3rd molar

surgery and the other one is performed on the second day after operation. Irradiation will be performed by positioning the laser probe in contact with the skin on four points of the masseter muscle: 1 -, lower region (near the mandibular insertion); 2 -, lower middle region; 3 -, upper middle region; and 4 -, upper region (near the insertion of the zygomatic arch). The laser will be applied for 7 minutes at each point.

Category

Treatment - Devices

2

Description

Intervention group: In the second group infra red laser(with the wavelength of 890 nm and the power of 6 joules per square centimeter) is applied extraorally on 2 occasions, once 30 minutes before the impacted lower 3rd molar surgery and the other one is performed on the second day after operation. Irradiation will be performed by positioning the laser probe in contact with the skin on four points of the masseter muscle: 1 -, lower region (near the mandibular insertion); 2 -, lower middle region; 3 -, upper middle region; and 4 -, upper region (near the insertion of the zygomatic arch).The laser will be applied for 5 minutes at each point.

Category

Treatment - Devices

3

Description

Control group: Placebo laser(off laser) is applied extraorally on 2 occasions, once 30 minutes before the impacted lower 3rd molar surgery and the other one is performed on the second day after operation. Placebo laser therapy will be performed by positioning the laser probe in contact with the skin on four points of the masseter muscle: 1 -, lower region (near the mandibular insertion); 2 -, lower middle region; 3 -, upper middle region; and 4 -, upper region (near the insertion of the zygomatic arch).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Tabriz University of Medical Sciences

Full name of responsible person

Javad Yazdani

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Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Tabriz 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
Tabriz University of Medical Sciences
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Position
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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available