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

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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.
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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
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Sponsors / Funding sources

1

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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
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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