Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of Low Level Laser Therapy (LLLT) in reducing symptoms after the surgery of the Mandibular Wisdom Tooth

Protocol summary

Study aim

The aim of this study is evaluation of effectiveness of Low Level Laser Therapy in reducing complications after the Mandibular Wisdom Tooth.

Design

Double blinded clinical trial randomised into 2 parallel groups with 72 samples from 36 patients

Settings and conduct

Patients of Dental Faculty of Guilan will be chosen if they are satisfied with inclusion criteria. The first therapist will perform surgerys and the second therapist is responsible for Laser Therapy to inform the analyst about receiving laser or not without knowledge of patients, the first and third therapist. The third therapist will measure the variables.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ASA 1 Patients with same level of Mandibular Third Molar in term of Pell & Gregory and Winter category Patients with good oral health without oral infection No alcoholic and smoker patients Patients under 40 years old Patients referred only for Wisdom Tooth Surgery Non inclusion criteria: Patients with ASA 2 and more Patients with acute Pericoronitis in past month Patients with chronic pain and Mental and Neurological illnesses Patients under Corticosteroid Therapy Patients with severe Periodental disease Patients with Pathology relative to adjacent tooth Patients with Allergy to local anesthesias or prescribed medicines in study Patients under treatment with Analgesic and Anti-inflammatory drugs In the cases of Laser Therapy contraception in patients Pregnant and breast feeding patients Patients who used Antibiotics or Analgesic other than determined protocol before surgery

Intervention groups

Samples are divided into two groups: Laser group and placebo group

Main outcome variables

Pain, Trismus , swelling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180826040872N1**
Registration date: **2019-03-03, 1397/12/12**
Registration timing: **prospective**

Last update: **2019-03-03, 1397/12/12**
Update count: **0**

Registration date

2019-03-03, 1397/12/12

Registrant information

Name

ali Khalighsigaroodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3333 0862

Email address

ali.khalighsigaroodi@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Low Level Laser Therapy (LLLT) in reducing symptoms after the surgery of the Mandibular Wisdom Tooth

Public title

Evaluation of effect of Laser in reducing symptoms of the Mandibular Wisdom tooth surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with ASA 1 Patients with same level of Mandibular Third Molar in term of Pell & Gregory and Winter category Patients with good oral health without oral infection No alcoholic and smoker patients Patients under 40 years old Patients referred only for Wisdom Tooth Surgery

Exclusion criteria:

Patients with ASA 2 and more Patients with acute Pericoronitis in past month Patients with chronic pain and Mental and Neurological illnesses Patients under Corticosteroid Therapy Patients with severe Periodental disease Patients with Pathology relative to adjacent tooth Patients with Allergy to local anesthesias or prescribed medicines in study Patients under treatment with Analgesic and Anti-inflammatory drugs In the cases of Laser Therapy contraception in patients Pregnant and breast feeding patients Patients who used Antibiotics or Analgesic other than determined protocol before surgery

Age

To **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **36**

More than 1 sample in each individual

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

In this study patients with bilateral Wisdom teeth will be chosen so that the Wisdom Tooth of one side will be placed in placebo group randomly and the other side will be as Laser group and this way individual characteristics will be eliminated. As a result 2 samples from each patient is taken and number of samples are 72 in the study.

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed by using R software by statistician and based on that Wisdom Tooth of one side (as surgical field) randomly will be placed in placebo group and the other side will be placed in Laser group

Blinding (investigator's opinion)

Double blinded

Blinding description

The first therapist (surgeon) will perform all surgerys and the second therapist after surgery will do Laser Therapy for Laser group and for placebo group he will put the handpiece on the field as it is off. The second therapist will inform the analyst about both groups receiving Laser or not (without knowledge of patients, first and third therapists). The third therapist will measure the variables.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of guilan university of medical sciences

Street address

Fuman_Saravan ring road, GUMS complex, dentistry faculty

City

rasht

Province

Guilan

Postal code

4188794755

Approval date

2019-01-12, 1397/10/22

Ethics committee reference number

IR.GUMS.REC.1397.402

Health conditions studied

1

Description of health condition studied

trismus after the Mandibular Wisdom Tooth surgery

ICD-10 code

R25.2

ICD-10 code description

Cramp and spasm

2

Description of health condition studied

extraction of mandibular wisdom tooth

ICD-10 code

K01.1

ICD-10 code description

Impacted teeth

Primary outcomes

1

Description
Score of pain in Baker Wong faces scale
Timepoint
Measurement of pain every 2 hours up to 6 hours after surgery and then once in the morning and once in the night before sleeping up to three days (at a specified hour)
Method of measurement
Baker Wong faces scale

2

Description
Trismus and opening rate of patient's mouth
Timepoint
Evaluation of trismus before surgery, first and seventh day after surgery
Method of measurement
The interval between right Maxillary and Mandibular Central Teeth will be measured by ruler (centimeter).

3

Description
Edema
Timepoint
Edema will be measured before surgery, first and seventh day after surgery.
Method of measurement
5 points are used: the Tragus, the Labial Commissure, the Lateral Canthus of eye, the Gonion and the pogonion. By using a piece yarn the intervals of Tragus to Labial Commissure, Lateral Canthus of eye to Gonion and Tragus to pogonion are measured and will be specified by rules (centimeter).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (Laser group): receiving Low Level Laser with 810 nm wavelength after the Mandibular Wisdom Tooth surgery
Category
Treatment - Devices

2

Description
Control group (placebo group): receiving placebo treatment (The handpiece is placed on the field of surgery but the appliance is off.)
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental Faculty of Guilan University of Medical science
Full name of responsible person
Arash Ghafoori
Street address
Rasht, Fuman-Saravan ring road, GUMS complex
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4188794755
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dental@gums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr Hamid Neshan Dar Asli
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dental@gums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences

Full name of responsible person
Donya maleki

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Dr Ali Khaligh Sigaroodi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Donya Maleki

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
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donyamaleki93@gmail.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
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
All data relative to measured index (pain, edema and trismus) are shared after unidentifying patients.

When the data will become available and for how long
6 months or 1 year after the publication of final results

To whom data/document is available
Anyone can access the data

Under which criteria data/document could be used
In order to design and perform similar research or as a base for more development studys

From where data/document is obtainable
Donya Maleki: donyamaleki93@gmail.com Dr Sigaroodi: Ali.khaligsigaroodi@gmail.ac.ir

What processes are involved for a request to access data/document
After sending an email and explaining about the study, they will receive the data in a month.

Comments