Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Determine the effect of low level laser therapy(LLLT) on pain, swelling and trismus after impacted mandibular third molar surgery

Protocol summary

Study aim
Evaluation of the effect of low power laser (LLLT) on pain, swelling and trismus after mandibular third molars

Design
The clinical trial is of the split mouth type and is performed as a blind strain. Randomized is a simple randomization performed on 38 patients.

Settings and conduct
This study was performed at Birjand Dental School as a bilateral surgical incision of the mandibular third molars in which the patients were blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients referred to the surgery department of Birjand Dental School are of both sexes who willingly want to remove the impacted mandibular teeth on both sides. Exclusion criteria: Patients with any systemic disease

Intervention groups
The intervention in this study is a low-power laser (LLLT) that is randomly given to one side of a patient's mouth. In this study, patients are in both the control and intervention groups, with one side of the patient's mouth randomly placed in the intervention group and the other side in the control group. Laser is used in the intervention group after surgery and placebo is used in the control group after surgery.

Main outcome variables
the pain ; Inflation; Trismus

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210928052620N1**
Registration date: **2021-12-13, 1400/09/22**
Registration timing: **retrospective**
Last update: **2021-12-13, 1400/09/22**
Update count: **0**

Registration date
2021-12-13, 1400/09/22

Registrant information

Name
amirmohammad chaji

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 56 3240 6292

Email address
chajiamirmohammad@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-30, 1399/09/10

Expected recruitment end date
2021-05-26, 1400/03/05

Actual recruitment start date
2021-02-03, 1399/11/15

Actual recruitment end date
2021-09-28, 1400/07/06

Trial completion date
2021-09-28, 1400/07/06

Scientific title
Determine the effect of low level laser therapy(LLLT) on pain, swelling and trismus after impacted mandibular third molar surgery

Public title
Evaluation of The effect of low power laser (LLLT) on complications after mandibular third molars

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients of both sexes are willingly willing to remove impacted mandibular on both sides. Patients who have the same position and inclination of the impacted molars on both sides of the mandible.
Exclusion criteria:
Patients with any systemic disease Patients who have been taking corticosteroids for more than 3 months.

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **38**
More than 1 sample in each individual
Number of samples in each individual: **2**
Bilateral surgery of impacted mandibular third molars
Actual sample size reached: **38**
More than 1 sample in each individual
Actual sample size in each individual: **2**
Bilateral surgery of impacted mandibular third molars

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization. Sealed by envelope method. We put the names of the patients in the sealed envelope and by drawing lots, the first half of the patients whose names came out of the envelope were on the right side of their mouths in the intervention group and the second half of the patients were the other way around.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, patients are blind.

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Birjand university of medical sciences

Street address
Pamchal Blvd, pamchal 4, No.53

City
Birjand

Province
South Khorasan

Postal code
9717411143

Approval date
2021-01-09, 1399/10/20

Ethics committee reference number
IR.BUMS.REC.1399.454

Health conditions studied

1

Description of health condition studied
Bilateral surgery of impacted mandibular third molars

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The primary variable is the amount of pain based on the visual analog system (VAS), which is asked of the patient on a scale of 0 to 10.

Timepoint
Days 2 and 7 after surgery

Method of measurement
Use the VAS system to measure pain

2

Description
Another primary consequence variable is the amount of swelling, which is measured by measuring the distance from the corner of the eye to the angle of the jaw on the same side and the distance from the ear hole to the corner of the lip on the same side using a ruler or meter.

Timepoint
Days 2 and 7 after surgery

Method of measurement
Use a meter or ruler to measure inflation

3

Description
Another primary outcome variable is the amount of trismus, which measures the amount of mouth opening using a ruler or meter.

Timepoint
Days 2 and 7 after surgery

Method of measurement
Use a meter or ruler to measure the amount of trismus

Secondary outcomes

1

Description
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Timepoint

–

Method of measurement

–

Intervention groups

1

Description

Intervention group: The intervention in this study is the use of low power laser. The type of study is split mouth in such a way that for each patient a laser (intervention) is used for one side of the wisdom tooth and a placebo is used for the opposite side. Our intervention is a low-power arsenide-gallium laser that the surgeon uses immediately after surgery and suturing the surgical site at 5 points with a power density of 52.5 joules for 30 seconds (for each point).

Category

Treatment - Other

2

Description

Control group: In our study, each person is both within the intervention group and the control group. Randomly, one side of each patient's mouth is in the intervention group and the other side is in the control group. Here, a part of the mouth that is in the control group uses a silent laser (placebo) after the surgery (the patient is blind).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Birjand Dental School

Full name of responsible person

amirmohammad chaji

Street address

Pamchal Blvd, pamchal 4, No.53

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Hamid abbaszade

Street address

Pamchal Blvd, pamchal4, N0.53

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

amirmohammad chaji

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Position
student

Latest degree
A Level or less

Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person
Amirmohammad chaji

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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
Not applicable

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
Not applicable

Title and more details about the data/document
Information about the main outcome and patient records can be shared. Informed consent form, clinical study results, study protocol and codes used in the study are fully available.

When the data will become available and for how long
Access period starts 6 months after the results are published

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
Changes in initial outcomes cannot be cited in other studies because they are time-dependent. The final results of the study provide a suggestion for more detailed studies with greater scope and longer follow-up.

From where data/document is obtainable
chajiamirmohammad@gamil.com
mohamadi_moghadam@yahoo.com

What processes are involved for a request to access data/document
Sending the content of the email, including the name of the researcher, the name of the study or the reason for interest, and documents related to the academic researcher, if you see the email, the documents will be sent up to one month later.

Comments