

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of low intensity laser therapy on trismus and swelling after impacted mandibular third molar surgery

Protocol summary

Study aim

The evaluation of Doctor Smile WISER/LA3D0 001.3 Diode laser on swelling and trismus after impacted third molar surgery

Design

A clinical trial with two groups of intervention (laser irradiation) and control (no irradiation), Randomized double-blinded, . The 40 enrolled individuals were randomized and sex matched into two groups of laser and control.

Settings and conduct

All surgeries and laser irradiations were done by one surgeon in both groups measurements will do by dental student unaware from process

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18-25 years of age and complete systemic health with mesio-angular Class II, I and A third molar tooth impaction Exclusion criteria: Systemic disease, local infection such as pericoronitis, history of using drugs such as NSAIDs up to 12 hours before surgery, use of contraceptives, pregnancy or lactation

Intervention groups

The emission of low level laser after surgical removal of third molars intraorally and extraorally and use of ordinary light of laser device on control group.

Main outcome variables

Swelling: the horizontal distance between lip commissure and auricle and the vertical distance between lateral cantus and mandibular angle ; Trismus distance between incisal edges of upper and lower centrals

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180920041076N1**

Registration date: **2019-10-05, 1398/07/13**

Registration timing: **retrospective**

Last update: **2019-10-05, 1398/07/13**

Update count: **0**

Registration date

2019-10-05, 1398/07/13

Registrant information

Name

Hadi hashem zehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3824 1949

Email address

h.hashemzehi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

2015-07-11, 1394/04/20

Actual recruitment end date

2015-12-19, 1394/09/28

Trial completion date

2016-02-03, 1394/11/14

Scientific title

Evaluation of low intensity laser therapy on trismus and swelling after impacted mandibular third molar surgery

Public title

Effect of laser in dental surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-25 years of age Mesio-angular Class I or II, A impacted

third molar

Exclusion criteria:

systemic disease local infection smoking pregnancy
lactation use of drugs such as contraceptives or NSAIDS

Age

From **18 years** old to **25 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified randomization was used for gender matching. Then they were simply randomized into the two intervention and control groups. The unit of randomization was individual and sealed envelopes were used as a randomization tool.

Blinding (investigator's opinion)

Double blinded

Blinding description

All patients inform that in this study they are irradiated by laser randomly and a laser that was not on was used in the control group without their awareness, therefore in both groups we stimulated the use of lase the The college who measures the data was also unaware.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences

Street address

Dr Hesabi Blvd.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2015-06-28, 1394/04/07

Ethics committee reference number

7392

Health conditions studied

1

Description of health condition studied

Trismus and swelling after surgical removal of third molar

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Inter-incisal distance of the jaws

Timepoint

Before surgery,2 and 7 days after surgery

Method of measurement

By a ruler

2

Description

The horizontal distance between lip commissure and auricle

Timepoint

Before surgery,2 and 7 days after surgery

Method of measurement

By a ruler and silk suture

3

Description

The vertical distance between lateral cantus and mandibular angle

Timepoint

Before surgery,2 and 7 days after surgery

Method of measurement

By a ruler and silk suture

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A Doctor Smile WISER/ (LAMBDA Scientifica S.r.l,Italy) 980 nm laser with a setting of CW, at 200mw for 60s of irradiation was given from a 1 cm distance with a Flattop therapy hand piece (12J/cm2), intraorally on the buccal and lingual sides of the treated site and also extraorally on the masseter muscle insertion site with a with a continuous wave mode(a total of 36J/cm2).

Category

Treatment - Devices

2

Description

Control group: A laser that was not on was placed in the same areas (Intra-orally on the Buccal and Lingual of the surgical area and extra-orally on the Master muscle) to create similar conditions for the patients.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Zahedan University of Medical Sciences, Zahedan
School of Dentistry

Full name of responsible person

Kimya Arab

Street address

Mehr Ave

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Sistan-va-Balouchestan

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Email

dentistry@zaums.ac.ir

Web page address

<http://www.dent.zaums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Hooshang Rafighdoost

Street address

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public@zaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Hadi Hashem Zehi

Position

Assistante professor

Latest degree

Specialist

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Hadi Hashem Zehi

Position

Associated Professor

Latest degree

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Person responsible for updating data

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Position

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Latest degree

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Other areas of specialty/work

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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

IPD collected for the primary outcome measure only

When the data will become available and for how long

January 2017-January 2022

To whom data/document is available

Only available for people working in academic institutions

Under which criteria data/document could be used

all types of analysis are allowed

From where data/document is obtainable

by Email: hashemzehi@gmail.com

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

Will be answered by a maximum time of 2 months

Comments