Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 pericornitis, history of using drugs such as NSAIDs up to 12 hours before surgery, use of contraceptives, pregnancy or lactation

Intervention groups
The emmision of low level laser after surgical removal of third molars intraorally and extraorally and use of ordinary light of laser divice 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 colleuge 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 extraoraly 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
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Mehr Ave
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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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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
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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