

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Effect of low level 940 nm diode laser therapy on pain, swelling and trismus after concomitant bilateral sagittal split osteotomy of mandibular ramus and Le Fort 1 osteotomy: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of low level 940 nm diode laser therapy on pain, swelling and trismus after concomitant bilateral sagittal split osteotomy of mandibular ramus and Le Fort 1 osteotomy

Design

This is a randomized clinical trial, in which 30 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients who need for bilateral sagittal split osteotomy of mandibular ramus and Le Fort 1 osteotomy and will refer to the School of Dentistry in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 65 years; Need for bilateral sagittal split osteotomy of mandibular ramus and Le Fort 1 osteotomy; Pulling out the third molar 6 months ago Exclusion criteria: History of facial trauma; Disorder of inferior alveolar nerve; A history of gingivoplasty; Rapture of the neurovascular bundle; A history of split surgery BSSO; Disorder of temporomandibular joint

Intervention groups

Intervention group: Bilateral sagittal split osteotomy of mandibular ramus and Le Fort 1 osteotomy plus low level 940 nm diode laser therapy for at most 3 minutes
Control group: Bilateral sagittal split osteotomy of mandibular ramus and Le Fort 1 osteotomy

Main outcome variables

Assessing the severity of pain
Assessing the severity of swelling
Assessing the severity of trismus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N266**

Registration date: **2019-03-15, 1397/12/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-15, 1397/12/24**

Update count: **0**

Registration date

2019-03-15, 1397/12/24

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-11, 1397/12/20

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of low level 940 nm diode laser therapy on pain, swelling and trismus after concomitant bilateral sagittal split osteotomy of mandibular ramus and Le Fort 1 osteotomy: a randomized clinical trial

Public title

Effect of low level 940 nm diode laser therapy on pain, swelling and trismus after concomitant bilateral sagittal split osteotomy of mandibular ramus and Le Fort 1 osteotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years; Need for bilateral sagittal split osteotomy of mandibular ramus and Le Fort 1 osteotomy; Pulling out third molar 6 months ago

Exclusion criteria:

A history of facial trauma; Disorder of inferior alveolar nerve; A history of gingivoplasty; Rapture of neurovascular bundle; A history of split surgery BSSO; Disorder of temporomandibular joint

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the right and left sides of patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the right side of the patient will be assigned to that group and the opposite side to another group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2019-02-23, 1397/12/04

Ethics committee reference number

IR.UMSHA.REC.1397.893

Health conditions studied

1

Description of health condition studied

Limited mandibular range of motion

ICD-10 code

M26.52

ICD-10 code description

Limited mandibular range of motion

Primary outcomes

1

Description

Assessing the severity of pain

Timepoint

Immediately after surgery and then 72 hours and 1 and 2 and 4 weeks later

Method of measurement

By using the Visual Analog Scale

2

Description

Assessing the severity of swelling

Timepoint

Immediately after surgery and then 72 hours and 1 and 2 and 4 weeks later

Method of measurement

through the physical examination

3

Description

Assessing the severity of trismus

Timepoint

Immediately after surgery and then 72 hours and 1 and 2

and 4 weeks later

Method of measurement

Through the physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Bilateral sagittal split osteotomy of mandibular ramus and Le Fort 1 osteotomy plus low level 940 nm diode laser therapy for at most 3 minutes

Category

Treatment - Other

2

Description

Control group: Bilateral sagittal split osteotomy of mandibular ramus and Le Fort 1 osteotomy

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry in Hamadan City

Full name of responsible person

Navid Meimanat Abadi

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School of Dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Navid Meimanat Abadi

Position

Dentistry Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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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)**

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

Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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