Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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

Street address

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

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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 updating data

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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