

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Determination of the Effectiveness of Diode Laser 940 nm in Decreasing of Oropharyngeal Pain after Bimaxillary Orthognathic Surgery.

Protocol summary

Study aim

Determination of the effectiveness of diode laser 940 nm in decreasing of oropharyngeal pain after bimaxillary orthognathic surgery

Design

A concealed, four blocks randomized, double-blinded, controlled clinical trial with 40 patients, enrolled between May 2019 and December 2019.

Settings and conduct

This clinical trial will be done in Hamadan Besat hospital. Patients are allocated into two groups of control and intervention. Patients who have allocated in the intervention group will receive irradiation of 940 nm diode laser in the pharyngeal area immediately after Bimaxillary orthognathic surgery. In the control group, no intervention will occur.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are candidates for bimaxillary orthognathic surgery
Exclusion criteria: History of pain in the orofacial region before surgery; Taking analgesic, sedative, or corticosteroid before surgery; If surgery lasts more than 4 hours and less than 3 hours; If the intubation process repeats; If an anesthetic complication occurs; If a surgical complication occurs.

Intervention groups

Patients who have allocated in the intervention group will receive irradiation of 940 nm diode laser in the pharyngeal area immediately after Bimaxillary orthognathic surgery. In the control group, no intervention will occur.

Main outcome variables

Pharyngeal region pain
Maxillary and/or mandibular regions pain
Pain during swallowing
Stridor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120531009926N9**

Registration date: **2020-10-19, 1399/07/28**

Registration timing: **retrospective**

Last update: **2020-10-19, 1399/07/28**

Update count: **0**

Registration date

2020-10-19, 1399/07/28

Registrant information

Name

Mohammad Reza Jamalpour

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-10, 1398/02/20

Expected recruitment end date

2019-12-31, 1398/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of the Effectiveness of Diode Laser 940 nm in Decreasing of Oropharyngeal Pain after Bimaxillary Orthognathic Surgery.

Public title

Effect of Diode Laser 940 nm in Decreasing of Oropharyngeal Pain after Orthognathic Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who are candidates for bimaxillary orthognathic surgery.

Exclusion criteria:

History of pain in the orofacial region before surgery
Taking analgesic, sedative, or corticosteroid before surgery
If surgery lasts more than 4 hours and less than 3 hours
If the intubation process repeats
If an anesthetic complication occurs
If a surgical complication occurs

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Each patient as a unit of randomization will be allocated in group A or B through four blocks. Concealment will be done by sealed envelope. The sequence of blocks will be determined with software.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

WHO International Clinical Trials Registry

Secondary trial Id

ACTRN1261600143646op " for ANZCTR

Registration date

2022-03-20, 1400/12/29

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan Medical Sciences University

Street address

Oral and Maxillofacial Surgery Department- Hamadan Medical Sciences University- Shahid Fahmideh Blv- Hamadan

City

Hamadan

Province

Hamadan

Postal code

65166852369

Approval date

2019-05-04, 1398/02/14

Ethics committee reference number

IR.UMSHA.REC.1398.096

Health conditions studied

1

Description of health condition studied

Pain in the oropharynx after simultaneous surgery of the two jaws

ICD-10 code

Code R07.0

ICD-10 code description

ICD-10-CM Diagnosis Code R07.0: Pain in throat

2

Description of health condition studied

Pain in the oropharynx after simultaneous surgery of the two jaws

ICD-10 code

Code R07.0

ICD-10 code description

ICD-10-CM Diagnosis Code R07.0: Pain in throat

Primary outcomes

1

Description

Oropharyngeal pain

Timepoint

First, second, third, fourth and fifth days after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Pain in maxillary and/or mandibular regions

Timepoint

First, second, third, fourth and fifth days after surgery

Method of measurement

Visual Analogue Scale

2

Description

Pain during swallowing

Timepoint

First, second, third, fourth and fifth days after surgery

Method of measurement

Visual Analogue Scale

3**Description**

Stridor

Timepoint

First, second, third, fourth and fifth days after surgery

Method of measurement

Listening

Intervention groups**1****Description**

Patients in the intervention group will be irradiated in the oropharyngeal region with 940 laser (Biolase, USA) immediately after surgery and before removal of the nasopharyngeal tube. Irradiation will be done continuously on all regions of oropharyngeal walls i.e posterior wall, lateral walls and posterior of the tongue. Irradiation will be fulfilled with a regular head and without contact to skin or mucosa. Output power is 100 w and spot size is 0.5 cm². Irradiation time in each region is 20 s and power density is 0.2 w/ cm².

Category

Treatment - Surgery

2**Description**

Control group: In patients in the control group, after laser surgery of both jaws, no 940 diode laser radiation (Biolase, USA) is performed in the oropharynx.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Besat Hospital

Full name of responsible person

Mohammad Reza Jamalpour

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Shahid Beheshti street, Besat hospital

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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

Private

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

Mohammad Reza Jamalpour

Position

Associate professor of Oral and Maxillofacial surgery
Department

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

Medical Education

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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

In the intervention group, a 940 nm diode laser is applied to the oropharynx after simultaneous surgery, and the pain in the oropharynx is measured after the operation.

When the data will become available and for how long

In the first to fifth days after surgery

To whom data/document is available

Doctors, assistants and students

Under which criteria data/document could be used

Merely the development of science and research

From where data/document is obtainable

surgery room

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

1- Patient selection 2- Treatment plan 3- Anesthesia process 4- Surgery 5- Laser irradiation 6. Pain measurement

Comments