

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of 810 nm diode laser and pharyngeal pack on reducing oropharyngeal pain, cough and vomiting in patients after bimaxillary orthognathic surgery in patients receiving laser and patients without pharyngeal pack compared to patients with pharyngeal pack and without receiving laser: a randomized clinical trial study

Protocol summary

Study aim

Investigating the effect of 810 nm diode laser in reducing pain after Bimaxillary orthognathic surgery in the oropharynx region

Design

A concealed, controlled, double-blind, randomized clinical trial study will be conducted on 30 patients. The randomization function of Excel software was used for randomization.

Settings and conduct

Patients of each group are subjected to Bimaxillary surgery with similar conditions in terms of nasopharyngeal intubation. In group A patients, the pharyngeal pack was not used during the operation and they will not receive radiation after the operation. Group B patients with pharyngeal packing during surgery and immediately after surgery are treated with photobiomodulation of the oropharynx area by 810 nm diode laser. In group C patients, a pharyngeal pack is placed during the operation, but no radiation will be applied. All patients of each group are asked to rate the amount of pain they feel in the throat area based on the Visual Analogue Scale index in hours after the operation in the information form that they will be given to register. The study was double-blind, the patient, the project partner who collects the information forms, and the statistician are unaware of the radiation or non-radiation of the laser on the patient.

Participants/Inclusion and exclusion criteria

Patients who are candidates for bimaxillary orthognathic surgery; did not have any problems in the area before and did not take related drugs.

Intervention groups

It includes an intervention group receiving 810 nm diode laser after the operation and having a pharyngeal pack

during the operation, an intervention group without receiving a laser and without a pharyngeal pack, and a control group with a pharyngeal pack and not receiving laser.

Main outcome variables

Pain in the oropharynx, pain in the jaw, pain in the oropharynx when swallowing saliva, the amount of coughing, nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220707055408N1**

Registration date: **2022-10-22, 1401/07/30**

Registration timing: **registered_while_recruiting**

Last update: **2022-10-22, 1401/07/30**

Update count: **0**

Registration date

2022-10-22, 1401/07/30

Registrant information

Name

mohamad hosein biglarkhani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1074

Email address

mhbglarkhani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-27, 1401/06/05

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of 810 nm diode laser and pharyngeal pack on reducing oropharyngeal pain, cough and vomiting in patients after bimaxillary orthognathic surgery in patients receiving laser and patients without pharyngeal pack compared to patients with pharyngeal pack and without receiving laser: a randomized clinical trial study

Public title

effect of laser 810 nm in orthognathic surgery side effects

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between 17 and 40 years old are candidates for bimaxillary orthognathic surgery

Exclusion criteria:

Patients who have a history of pain in the mouth and face before surgery Patients who have been treated with analgesics, sedatives or corticosteroids before the operation

Age

From **17 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Online randomization The numbers of the patients present in the study were entered on the Randomization.com website and were randomly and non-repeatedly divided into two intervention and control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patients participating in the study were

unaware of the assignment of the study group to them despite the prior knowledge of participating in the research. Also, the researcher and data analyst who examines the results and data obtained from each patient are also blinded to the assignment of the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Fahmideh St., Hamedan University of Medical Sciences

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Approval date

2022-05-21, 1401/02/31

Ethics committee reference number

IR.UMSHA.REC.1401.203

Health conditions studied

1

Description of health condition studied

Oropharyngeal pain after Bimaxillary orthognathic surgery

ICD-10 code

R07.0

ICD-10 code description

Pain in throat

Primary outcomes

1

Description

The pain score of study subjects in throat and jaw areas

Timepoint

The second, fourth, twelfth, twenty-fourth and forty-eighth hours after the operation

Method of measurement

Pain questionnaire based on Visual Analogue Scale

Secondary outcomes

1

Description

The degree of nausea and vomiting

Timepoint

The second, fourth, twelfth, twenty-fourth and forty-eighth hours after the operation

Method of measurement

Short questionnaire with 5 questions

2

Description

The number of coughs after the operation

Timepoint

The second, fourth, twelfth, twenty-fourth and forty-eighth hours after the operation

Method of measurement

Short questionnaire with 5 questions

Intervention groups

1

Description

first Intervention group: The group receiving 810 nm diode laser radiation in the oropharynx areas, the radiation is done immediately after the operation, the radiation time in each area is 20 seconds and power density will be 0.2 watt per cubic centimeter

Category

Rehabilitation

2

Description

Second Intervention group: the group with pharyngeal pack during surgery

Category

Rehabilitation

3

Description

Control group: The group without pharyngeal pack during surgery and not receiving laser radiation after surgery

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ofogh Surgery Clinic

Full name of responsible person

Mohammad Reza Jamalpour

Street address

Ofogh Clinic, Resalat Blvd

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Phone

+98 81 3262 2064

Email

jamalpour1972@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokoohi

Street address

Hamedan University of Medical Sciences, Fahmideh St.

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Phone

+98 81 3131 0000

Email

Webda@umsha.ac.ir

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

Mohamad Hosein Biglarkhani

Position

Doctor of Dental Surgery

Latest degree

Medical doctor
Other areas of specialty/work
Dentistry
Street address
No. 493, Haghgouyan St., Mahdiyeh St.
City
Hamedan
Province
Hamadan
Postal code
6517719743
Phone
+98 81 3837 2242
Email
mhbiglarkhani@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mohammad Reza Jamalpour
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Oral and Maxillofacial Surgery
Street address
Fahmideh St. Hamedan university of Medical Sciences
City
Hamedan
Province
Hamadan
Postal code
۶۵۱۷۸۳۸۷۳۶
Phone
+98 81 3131 0000
Email
jamalpour1972@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Mohamad Hosein Biglarkhani
Position
Doctor of Dental Surgery
Latest degree
Medical doctor
Other areas of specialty/work

Dentistry
Street address
No. 493, Haghgouyan St., Mahdiyeh St.
City
Hamedan
Province
Hamadan
Postal code
6517719743
Phone
+98 81 3837 2242
Email
mhbiglarkhani@gmail.com

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 810 nm diode laser is applied to the oropharynx after simultaneous surgery, and the pain in the oropharynx, vomiting and cough is measured after the operation

When the data will become available and for how long

After publishing the results of research

To whom data/document is available

Doctors, Residents, Students

Under which criteria data/document could be used

Development of science and research

From where data/document is obtainable

Department of Oral and Maxillofacial Surgery, Hamadan Faculty of Dentistry

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

1- Communicating with the general respondent of the research through email address 2- Refer to the oral and maxillofacial surgery department of the Faculty of Dentistry located in Hamadan University of Medical Sciences 3- Introduce yourself and receive the research documents from the person in charge of the information archive

Comments