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 rand function of Excel software was used for randomization.

Settings and conduct

Patients of each groups are subjected to Bimaxillary surgery with similar conditions in terms of nasopharyngeal intubation in. 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 groups 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)

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Mohamad Hosein Biglarkhani
Position
Doctor of Dental Surgery
Latest degree

Medical doctor
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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 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