Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of low level laser in the treatment of class II patients with mandibular deficiency treated with Farmand functional appliance

Protocol summary

Study aim

study the effect of low level laser in the treatment of class II patients with mandibular deficiency treated with Farmand functional appliance

Design

Clinical trial,with two groups(Farmand,Farmand+laser),factorial groups, double-blind, randomized on 22 patients. Graph pad software will be used for randomization.

Settings and conduct

The study is performed in Shahid Sadouqi Dental School of Yazd. After construction of Farmand appliance, lateral cephalometric radiography is taken for each patient. Patients of first group(Farmand)use only the functional appliance. For second group(Farmand+laser)after 1month of using the appliance until the end of treatment,once a week(12 sessions) laser(GaA1As 980nm diode)is irradiated at 4 points around the TMJ and 100 seconds for each point. After the period of functional therapy(6 months)radiographs are taken again from all patients and then we measure specific quantities in the pre and post treatment radiographs. Except the laser device operator,patients(in first group,laser applicator without radiation are placed),therapist,researcher and data analyst are unaware of which patient receive the laser.

Participants/Inclusion and exclusion criteria

Inclusion: 1- Age range 10to13 years for girls and 11to14 years for boys 2- Patient's profile in clinical view shows the pattern of skeletal class II with mandibular deficiency. 3- Dental canine and molar class II relationship. Non inclusion: 1- History of diseases affecting the growth process 2- History of jaw surgery 3- History of trauma to skull and face

Intervention groups

Control group(11patients)is treated with Farmand appliance and intervention group(11patients),in addition to Farmand appliance, also receive laser irradiation.

Main outcome variables

More growth of mandible in laser group (increase of Co-Gn variable in laser group compared to Farmand group)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210221050435N1**
Registration date: **2021-04-04, 1400/01/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-04, 1400/01/15**
Update count: **0**

Registration date

2021-04-04, 1400/01/15

Registrant information

Name
Hossein Aghili
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 35 3824 1785
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hosseinaghily@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-05, 1399/12/15

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of low level laser in the treatment of class II patients with mandibular deficiency treated with Farmand functional appliance

Public title

The effect of low level laser on mandibular growth in patients treated with functional appliance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 10 to 13 years for girls and 11 to 14 years for boys The patient profile in clinical view show the pattern of skeletal class II with mandibular deficiency so that the patient with retrognathic appearance has more acceptance profile after bringing the mandible forward. The patient has dental canine and molar class II relationship

Exclusion criteria:

History of disease affected the growth process History of jaw surgery History of trauma to skull and face

Age

From **10 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

First, using Random allocation software version 1.0 under Windows ,we generate a random sequence using a simple random allocation method. In this table, it is specified from 1 to 22 and each number is assigned to an intervention group (A or B). The first eligible patient is assigned number 1, the second patient is assigned number 2 and so on up to 22 patients. In order to blind the random allocation of clients by a third person who is unaware of the interventions, they are placed in intervention groups (A or B) by this table.

Blinding (investigator's opinion)

Double blinded

Blinding description

In our study, patients are unaware of which group they are in (Farmand group or Farmand + laser group) because all patients, even those who does not include laser receiving, are in the same situation to receive the laser, except that we placed the applicator of laser in specific places, but without laser radiation. In this study, with the exception of the laser device operator (who is aware of the laser irradiation or non-irradiation), the researcher (who is also responsible for treating the patients), the data collector, and the statistics consultant, who is responsible for analyzing the data, all are unaware of which group each patient belonged to.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Yazd Shahid sadoughi University of medical science

Street address

central building of shahid sadoughi university of medical science and health services-Bahonar square-Yazd

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2019-05-25, 1398/03/04

Ethics committee reference number

IR.SSU.REC.1398.025

Health conditions studied

1

Description of health condition studied

mandibular deficiency

ICD-10 code

M27.0

ICD-10 code description

Developmental disorders of jaws

Primary outcomes

1

Description

Increase rate of Co-Gn variable

Timepoint

Measurement of Co-Gn variable at the beginning of study (before the start of intervention) and after the end of

functional appliance treatment period (after 6 months)

Method of measurement

Measurement on lateral cephalometric radiographs using a ruler and conveyor

2

Description

Increase rate of ANB variable

Timepoint

Measurement of ANB variable at the beginning of study (before the start of intervention) and after the end of functional appliance treatment period (after 6 months)

Method of measurement

Measurement on lateral cephalometric radiographs using a ruler and conveyor

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After the Farmand functional appliances are made for each patient, they are trained to use the appliance 24 hours a day, except when eating, exercising, and brushing. The laser used in this study is diode (GaA1As) (A.R.C. Laser, Deutschland, Nurberg) with a wavelength of 980 nm, the output power of 100 mw. After one month of using the appliance, until the end of treatment, once a week (12 sessions) laser with the above characteristics is irradiated. Radiation is performed accurately and continuously by contact method at 4 points around the temporomandibular joint (upper, anterior, posterior, posterior) and 100 seconds for each point.

Category

Treatment - Devices

2

Description

Control group: We place the patients in control group in the same conditions (constructing a functional appliance, training for use, starting treatment with a functional appliance and presence at laser treatment sessions) with the difference that we place only the laser applicator in the mentioned points but without laser radiation.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Orthodontics, School of Dentistry, Shahid Sadoughi University of Medical Sciences, Yaz

Full name of responsible person

Hossein agha Aghili

Street address

The beginning of Deh Fajr Boulevard, Imam Khomeini St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr.Masoud Mirzaei

Street address

The headquarters of Shahid Sadoughi University of Medical Sciences and Health Services, Bahonar Square, Yazd

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Email

dvc.research@ssu.ac.ir

Web page address

https://web.ssu.ac.ir/index.aspx?lang=1&sub=21

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Hossein agha Aghili

Position
Associate professor

Latest degree
Specialist

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)
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
after unidentifying, It is possible to share all lateral cephalometric variables of patients before and after treatment.

When the data will become available and for how long
Start the access period 6 months after publishing the results

To whom data/document is available
Researchers working in academic and scientific institutions and valid scientific research journals

Under which criteria data/document could be used
In order to use the documents of this study for other studies and researches to apply the results

From where data/document is obtainable
Responsible person in this field: Mohadeseh Sharifi , email address: Sharifimohadeseh@yahoo.com

What processes are involved for a request to access

data/document

The applicant can send his request to the above-mentioned email address with his introduction and the reason for the request and receive the information as soon as possible (finally within 7-10 days).

Comments