

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of carbon dioxide laser on increasing vestibular depth in cleft lip and palate patients

Protocol summary

Registration timing: **prospective**

Study aim

The aim of this study was to evaluate the efficacy of CO2 laser for vestibuloplasty in the anterior region of the maxilla in cleft patients and also increase in the length of the upper lip in these patients

Last update: **2018-04-13, 1397/01/24**

Update count: **0**

Registration date

2018-04-13, 1397/01/24

Design

This clinical trial study, cleft lip and palate patients with shallow vestibule depth undergo CO2 laser surgery and the depth of the vestibule are measured before surgery, one week and four months after surgery. This study did not have control group

Registrant information

Name

soghra yassaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

s.yassaei@ssu.ac.ir

Settings and conduct

Cleft lip and palate patients presenting to the Department of Orthodontics of Yazd University of Medical sciences who had vestibular depth loss in the anterior maxilla are included in the study. The surgery is performed using CO2 laser for increasing vestibule depth, then measure the depth of the vestibule and the length of the lips in three steps in these patients by the digital caliper.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion criteria: Cleft and lip patients who had vestibular depth loss in the anterior maxilla following primary cleft surgery. Exclusion criteria: Patients who had already underwent secondary surgery for vestibuloplasty and subjects with certain systemic problems

Expected recruitment start date

2018-04-19, 1397/01/30

Expected recruitment end date

2018-06-20, 1397/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

15 patients undergo CO2 laser surgery to increase the depth of the vestibule in the anterior maxilla area.

Scientific title

Effect of carbon dioxide laser on increasing vestibular depth in cleft lip and palate patients

Main outcome variables

vestibule depth, upper lip length

Public title

Effect of CO2 laser on vestibule depth

Purpose

Treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180314039089N1**

Registration date: **2018-04-13, 1397/01/24**

Inclusion/Exclusion criteria

Inclusion criteria:

Cleft lip and palate patients presenting to the Department of Orthodontics of Yazd University of Medical sciences have vestibular depth loss in the anterior maxilla following primary cleft surgery

Exclusion criteria:

Patients who had already undergone secondary surgery for vestibuloplasty subjects with certain systemic problems heart disease (pacemaker) pregnancy epileptic seizures thyroid gland disease malignancies

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 15

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Sadoughi Yazd university of medical Science

Street address

Central organization Shahid Sadoughi Yazd University of Medical Sciences, Shahid Bahonar Square, Yazd

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2015-04-13, 1394/01/24

Ethics committee reference number

IR.SSU.REC.1394.17438

Health conditions studied

1

Description of health condition studied

vestibule deformity

ICD-10 code

H81

ICD-10 code description

Disorders of vestibular function

Primary outcomes

1

Description

vestibular depth

Timepoint

before surgery, 1 week following surgery, 4 months following surgery

Method of measurement

digital caliper

2

Description

upper lip length

Timepoint

before surgery, 1 week following surgery, 4 months following surgery

Method of measurement

digital caliper

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, CO2 laser with wavelength 10.600 nm, with output power of 5 W and continuous mode used for surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Shahid Sadoughi Yazd University of Medical Sciences

Full name of responsible person

Isa Safari

Street address

Shahid Sadoughi Dental University, Daheye Fajr Blvd., Emam Ave., Yazd

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Postal code
8914815667
Phone
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Email
isasafari1365@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Alireza Danesh Kazemi

Street address
Shahid Sadoughi Dental University, Daheye Fajr Blvd.,
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adaneshkazemi@yahoo.com

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
Isa Safari

Position
Orthodontic dentistry resident

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Soghra Yassaei

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

Contact

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Position
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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

All outcome are publised

When the data will become available and for how long

1398

To whom data/document is available

researchers in university and journals

Under which criteria data/document could be used

for verification and use in systematic review studies

From where data/document is obtainable

via email syassaeiQgmail.com

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

approximately one month

Comments