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

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

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

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.

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

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

Main outcome variables
vestibule depth, upper lip length

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180314039089N1**
Registration date: **2018-04-13, 1397/01/24**
Registration timing: **prospective**

Last update: **2018-04-13, 1397/01/24**
Update count: **0**

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

Registrant information

Name
soghra yassaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

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

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

Public title
Effect of CO2 laser on vestibule depth

Purpose
Treatment

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 lossin the anterior maxilla following primary cleft surgery

Exclusion criteria:

Patients who had already underwent 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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd 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
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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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