

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Evaluation of lip movement in patients with unilateral cleft lip, before and after vestibuloplasty by Co2 laser

Protocol summary

Study aim

Evaluation of lip movement in patients with unilateral cleft lip, before and after vestibuloplasty by Co2 laser in patients referred to the School of Dentistry

Design

control group includes patients with unilateral or bilateral cleft lip before vestibuloplasty and the intervention group includes the same patients after vestibuloplasty. The sample size includes 20 people. This study does not have a second phase. The patients are people with cleft lip and palate who refer to the orthodontic department of Yazd Dental School and we have no involvement in what economic, social, etc. group these people belong to. There is no possibility of blindness.

Settings and conduct

In this study, which is a clinical trial before and after, 20 people with unilateral or bilateral cleft lip are studied. Samples will be selected from patients with cleft lip, referred to Yazd Dental School and according to the inclusion and exclusion criteria. Before the study, the method and purpose of the study are explained to the patient and written consent is obtained from the samples, patients are assured that all information is confidential, then the samples are entered into the study and how the lips move electromyographically. Will be checked. The patient's satisfaction with the results of the surgery is also measured by a questionnaire.

Participants/Inclusion and exclusion criteria

1- Patients with unilateral cleft lip referred to Yazd Dental School orthodontic department at the time of research 2- Age over 12 years Patients should not have a syndromic cleft. 4. Filling in the informed consent of the patient to enter the study

Intervention groups

The intervention group is the same as the control group, but after vestibuloplasty.

Main outcome variables

How to change lip movement after vestibuloplasty by co2 laser

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210321050751N1**

Registration date: **2021-05-15, 1400/02/25**

Registration timing: **prospective**

Last update: **2021-05-15, 1400/02/25**

Update count: **0**

Registration date

2021-05-15, 1400/02/25

Registrant information

Name

Soghra Yassaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3625 6975

Email address

syassaei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of lip movement in patients with unilateral cleft lip, before and after vestibuloplasty by Co2 laser

Public title

Evaluation of lip movement in patients with unilateral cleft lip, before and after vestibuloplasty by Co2 laser

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

1- Patients with unilateral cleft lip referred to Yazd Dental School orthodontic department at the time of research
Age over 12 years Patients should not have a syndromic cleft Filling in the informed consent of the patient to enter the study

Exclusion criteria:

Any illness and trauma that occurs in the samples after the start of the study and affects the movement of the lips. Reluctance to participate in the study

Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

Sample: Orbicularis oris muscle in the patient before and after the intervention

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

Yazd shahid sadoughi university of medical science

Street address

Yazd. Dahe fajr Boulevard. Imam Reza Street.shahid sadoughi university of medical science

City

yazd

Province

Yazd

Postal code

8914881167

Approval date

2021-02-21, 1399/12/03

Ethics committee reference number

IR.SSU.REC.1399.267

Health conditions studied

1

Description of health condition studied

Lip movement in patients with cleft lip

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Changes in lip muscle contraction and movement

Timepoint

Twenty days after vestibuloplasty

Method of measurement

Using electromyography

2

Description

Patient satisfaction with vestibuloplasty results

Timepoint

Twenty days after vestibuloplasty

Method of measurement

Using a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with unilateral or bilateral cleft lip and palate in which vestibuloplasty is performed as an intervention. Co2 laser is used to perform vestibuloplasty. After surgery, there is no need for sutures, the patient experiences little discomfort and There is no bleeding. This intervention will be performed only once in each patient.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Orthodontics, Shahid Sadoughi School of Dentistry, Yazd

Full name of responsible person

Elahe Salarpour

Street address

Yazd. Fajr Decade Boulevard. Imam Reza St.. Shahid Sadoughi Dental School of Yazd

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samat@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

maseud mirzaei

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Department of Orthodontics, Shahid Sadoughi School of Dentistry, Yazd

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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

elahe salarpour

Position

orthodontics resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Department of Orthodontics, Shahid Sadoughi School of Dentistry, Yazd

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

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Position

orthodontic resident

Latest degree

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Other areas of specialty/work

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City

yazd

Province

Yazd

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Phone

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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 variables of patients.

When the data will become available and for how long

After unidentifying ,it is possible to share all variables of patients.

To whom data/document is available

Researchers working in academic and scientific institutions and valid scientific research

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 and a step forward for the use of lasers in patients with cleft lip and palate

From where data/document is obtainable

elahe salarpour email:dr.elahe.salarpour@gmail.com

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

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

Comments