

# 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

**City**

yazd

**Province**

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**Postal code**

8914881167

**Phone**

+98 35 3625 5813

**Email**

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

**Street address**

Department of Orthodontics, Shahid Sadoughi School of Dentistry, Yazd

**City**

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**Province**

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**Email**

mmirzaei@ssu.ac.ir

**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

**City**

yazd

**Province**

Yazd

**Postal code**

8914881167

**Phone**

+98 34 3428 4157

**Email**

dr.elahe.salarpour@gmail.com

## Person responsible for scientific 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

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

elahe salarpour

**Position**

orthodontic resident

**Latest degree**

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**Other areas of specialty/work**

Dentistry

**Street address**

یزد، بلوار دهه فجر، خیابان امام رضا، دانشکده علوم پزشکی شهید صدوقی یزد.

**City**

yazd

**Province**

Yazd

**Postal code**

8914881167

**Phone**

+98 34 3428 4157

**Email**

dr.elahe.salarpour@gmail.com

## 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**