

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effect of lip exercise with activator headgear on the inter labial gap on class II division 1 and long face patients

Protocol summary

upper and lower lip length; upper and lower vermilium

Study aim

The aim was to investigate the effect of activator high pull headgear with lip exercises on closing the inter labial gap in patients with class II malocclusion and long face in 1400-99 at the Azad Dentistry University.

Design

This study is a clinical trial and we need 30 orthodontic patients. Patients are randomly divided into two groups of 15 with random number generator app. Which is a group as a control group and the groups are parallel.

Settings and conduct

All patients are photographed with the camera in natural head position mode in three frontal, frontal in smile and profile views. Then Inter-labial gap, upper and lower lip length, upper and lower lip vermilium were clinically calibrated with collis with a precision of 0.02 mm and the nasolabial angel and angel of convexity will be measured with the help of pictures. All patients are given an activator high pull headgear . A group of people will be taught the lip exercises that include placing the thumb inside the upper lip vestibule and the other 4 fingers outside the lip under the nose and pulling lips down for 20 seconds and also massage the upper lip downwards with the thumb for 20 seconds. The other group completes their treatment without lip training. The study groups are not aware of the presence of other participants in the study.

Participants/Inclusion and exclusion criteria

No history of orthodontic treatment; presence before the age of physical maturity defined for girls 9 to 11 years and for boys 10 to 12 years; skeletal class II; long face; lip incompetent

Intervention groups

Patients are randomly divided into two groups of 15 people, both groups are prescribed an activator headgear, and only one group will be taught the exercises to increase lip length.

Main outcome variables

inter labial gap; nasolabial angel; angel of convexity;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200707048046N1**

Registration date: **2021-01-19, 1399/10/30**

Registration timing: **prospective**

Last update: **2021-01-19, 1399/10/30**

Update count: **0**

Registration date

2021-01-19, 1399/10/30

Registrant information

Name

Atiye Safaralizade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 0210

Email address

aty.alizade@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of lip exercise with activator headgear on the inter labial gap on class II division 1 and long face patients

Public title

Effect of lip exercise with activator headgear on the inter labial gap on class II division 1 and long face patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Skeletal class II Div.1 Long face Lip incompetent

Exclusion criteria:

Orthodontic history

Age

From **9 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyster

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Samples that were entered into the intervention group according to the lottery will receive instructions on how to perform lip exercises without informing the other participants. Also, the person who analyzes the data will analyze the information without knowing the grouping of people and every person in each group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran Islamic Azad University of Dental Branch of Medical Sciences

Street address

No.9, Ninth Neyestan, Pasdaran Ave, Tehran, Tehran

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2020-09-30, 1399/07/09

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.183

Health conditions studied

1

Description of health condition studied

Orthodontic

ICD-10 code

Z46.4

ICD-10 code description

Encounter for fitting and adjustment of orthodontic device

Primary outcomes

1

Description

inter labial gap

Timepoint

At the time of receiving the orthodontic appliance and at the end of the treatment

Method of measurement

from patient with collis

2

Description

upper lip length

Timepoint

At the time of receiving the orthodontic appliance and at the end of the treatment

Method of measurement

from patient with collis

3

Description

upper lip Vermilium

Timepoint

At the time of receiving the orthodontic appliance and at the end of the treatment

Method of measurement

from patient with collis

4

Description

lower lip length

Timepoint

At the time of receiving the orthodontic appliance and at the end of the treatment

Method of measurement

from patient with collis

5

Description

lower lip vermilium

Timepoint

At the time of receiving the orthodontic appliance and at the end of the treatment

Method of measurement

from patient with collis

Secondary outcomes

1

Description

Nasolabial angle

Timepoint

During orthodontic treatment

Method of measurement

With a protractor from the image

2

Description

angle of convexity

Timepoint

During orthodontic treatment

Method of measurement

With a protractor from the image

Intervention groups

1

Description

Control group: receiving orthodontic appliance, activator high pull headgear and using it for 14 hours during the day

Category

Treatment - Devices

2

Description

Intervention group: Receiving orthodontic appliance along with the upper lip exercises so that it takes the upper lip with 4 fingers from the outside and the thumb from the inside and pulls it down for 20 seconds. Perform this exercise 3times a day and 5times each time.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Islamic Azad University of Dental Branch of Medical Sciences

Full name of responsible person

Dr. Afshin Haraji

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No.9, ninthth Neyestan, Pasdaran Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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<http://dental.iautmu.ac.ir/fa>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Atiye SafarAlizade

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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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Assistant professor

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Specialist

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Islamic Azad University

Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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