

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Aug 2026

effects of Continuous Positive Airway Pressure (CPAP) therapy on noncleft velopharyngeal dysfunction

Protocol summary

Study aim

Effects of CPAP therapy on hypernasal speech in non cleft velopharyngeal dysfunction

Design

This study is a single subject study design that will be performed on a patient with noncleft velopharyngeal dysfunction.

Settings and conduct

This study will be performed in the cleft lip and palate clinic of Isfahan University of Medical Sciences. This study has three phases: Baseline phase: Perceptual assessments of speech and nasometry are performed weekly for one month. Treatment Phase: CPAP treatment is done according to Dr. Kuehn's protocol within two months. Perceptual assessments of speech and nasometry are performed weekly. Follow up phase: Perceptual assessments of speech and nasometry are performed weekly for one month.

Participants/Inclusion and exclusion criteria

Non cleft velopharyngeal dysfunction: No occult submucous cleft palate: Mild or moderate hypernasality: No compensatory error: No hearing loss and ear dysfunction

Intervention groups

This study has no control group. CPAP treatment will be performed for two months according to Dr. Kuehn's protocol.

Main outcome variables

Hypernasality of speech: Nasalanse score of speech

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201223049809N1**

Registration date: **2021-02-08, 1399/11/20**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-08, 1399/11/20**

Update count: **0**

Registration date

2021-02-08, 1399/11/20

Registrant information

Name

Fatemeh Mostajeran

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3263 1405

Email address

f.mostajeran@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

effects of Continuous Positive Airway Pressure (CPAP) therapy on noncleft velopharyngeal dysfunction

Public title

Effects of CPAP therapy on hypernasal speech

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Non cleft velopharyngeal dysfunction Mild or moderate

hypernasality
Exclusion criteria:
No occult submucouse cleft palate No compensatory errors No hearing loss and ear dysfunction

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 1

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Method of the study is single subject design

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

سامانه ملی اخلاق در پژوهش های زیست پزشکی

Street address

No. 7, Sarvestan St., Jeyshir Ave.

City

Isfahan

Province

Isfahan

Postal code

8158165166

Approval date

2020-11-07, 1399/08/17

Ethics committee reference number

IR.MUI.MED.REC.1399.691

Health conditions studied

1

Description of health condition studied

Non cleft velopharyngeal dysfunction Hypernasal speech

ICD-10 code

MA82.2 Nas

ICD-10 code description

Nasality (or resonance) refers to the quality of the voice

that is determined by the balance of sound vibration in the oral, nasal, and pharyngeal cavities during speech. Abnormal resonance can occur when there is obstruction in one of the cavities, causi

Primary outcomes

1

Description

Hypernasality of speech

Timepoint

At the beginning of the study and then weekly for three months

Method of measurement

CAPS Test

Secondary outcomes

1

Description

Nasalance score

Timepoint

At the beginning of the study and then weekly for three months

Method of measurement

Nasometer

Intervention groups

1

Description

Intervention group: Continuous positive air pressure (CPAP) treatment using CPAP device (Resmed- S9) according to Dr. Kuehne protocol, 6 days a week for two months

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

کلینیک شکاف لب و کام اصفهان

Full name of responsible person

Fatemeh Khanlar

Street address

Rehabilitation institute, Isfahan univerity of medical sciences, Hezarjarib Ave.

City

Isfahan

Province

Isfahan

Postal code

81745-164

Phone

+98 31 3792 5224

Email
cleftresearchcenter@gmail.com
Web page address
https://icct.mui.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjouy Javanmard
Street address
Isfahan university of medical sciences, Hezarjarib Ave.
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3668 8138
Email
research@mui.ac.ir
Web page address
https://research.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Fatemeh Mostajeran
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Speech therapy
Street address

No. 7, Sarvestan St., Jeyshir Ave.

City

Isfahan

Province

Isfahan

Postal code

8158165166

Phone

+98 31 3263 1406

Email

f.mostajeran@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fatemeh Mostajeran
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Speech therapy
Street address
No. 7, Sarvestan St., Jeyshir Ave.
City
Isfahan
Province
Isfahan
Postal code
8158165166
Phone
+98 31 3263 1405
Email
f.mostajeran@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fatemeh Mostajeran
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Speech therapy
Street address
Rehabilitation Institute, Isfahan university of medical sciences, Hezarjarib Ave.
City
Isfahan
Province
Isfahan
Postal code
81745-164
Phone

+98 31 3792 5217

Email

f.mostajeran@gmail.com

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

Not applicable