Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of traditional and clear twin block on the speech of skeletal class II patients

Protocol summary

Study aim

The aim of this study is to compare the effect of traditional twin block and clear twin block on speech of class II skeletal patients.

Design

A randomized clinical trial with a control and parallel groups design of 18 patients, enrolled and followed for three months after starting treatment. Participants were blinded by how the groups were allocated.

Settings and conduct

The study will be performed on patients with class II malocclusion in Tabriz faculty of dentistry. To evaluate the effect of the appliance on patients' speech, the patient's speech will be evaluated at the times: before receiving the appliance, immediately after receiving the appliance, one month after receiving the appliance and three months after receiving the appliance. Speech assessment consists of two parts: vowels and syllables. Patients' speech samples will be recorded and then examined for vowel formants and number of distortions. Speech performance will be compared in two groups of control and intervention and the performance of each group will be compared at different times.

Participants/Inclusion and exclusion criteria

inclusion criteria: being literate, no cognitive problems, no cleft lip and palate, no neurological problems, no phonological and articulation problems and no hearing loss.

Intervention groups

treatment group: class II patients that use traditional twinblock appliance. control group: class II patients that use clear twinblock appliance.

Main outcome variables

first formants of vowels second formants of vowels third formants of vowels number of distortions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210927052606N1**
Registration date: **2021-10-25, 1400/08/03**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-25, 1400/08/03**
Update count: **0**

Registration date

2021-10-25, 1400/08/03

Registrant information

Name

Mahsa Zali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3442 7984

Email address

m.mahsa.zali@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-16, 1400/07/24

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of traditional and clear twin block on the speech of skeletal class II patients

Public title
Comparison of the effect of traditional and clear twin block on the speech of skeletal class II patients
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
being literate no cognitive problems no cleft lip and palate no neurological problems no articulation and phonological disorders no hearing loss
Exclusion criteria:
Age
From **9 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **18**
Randomization (investigator's opinion)
Randomized
Randomization description
simple randomization method will be used and, groups assingments will be determined by flipping coin.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants do not know about the allocation of study groups. What device each patient receives is selected randomly by another person without their knowledge. The patient is not aware that he is in the case or control group, but the researchers are aware.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o
Street address
No. 26, avval ordibehesht alley ., 22bahman Ave., tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5178647435
Approval date
2021-03-12, 1399/12/22
Ethics committee reference number
IR.TUMS.FNM.REC.1399.236

Health conditions studied

1

Description of health condition studied
class II malocclusion
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Number of malfunctions: The number of sounds that have been altered and the sound produced is not phonetically accurate enough.
Timepoint
Before - immediately - one month and three months after receiving the appliance.
Method of measurement
Recording with microphone praat software.

2

Description
First Formant of vowels: A formant that relates to the height of the tongue when producing a vowel.
Timepoint
Before - immediately - one month and three months after receiving the appliance.
Method of measurement
Recording with microphone praat software.

3

Description
Second Formant of vowels: A formant that relates to the amount of tongue protrusion when producing a vowel.
Timepoint
Before - immediately - one month and three months after receiving the appliance.
Method of measurement
Recording with microphone praat software.

4

Description
Third Formant of vowels: A formant that relates to the amount of roundness of the lips when producing a vowel.
Timepoint
Before - immediately - one month and three months after receiving the appliance.
Method of measurement
Recording with microphone praat software.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The group that receives the clear twin block appliance. This device should be used by the patient at all times except when eating and brushing.
Category
Treatment - Devices

2

Description
Control group: The group that receives the traditional twin block appliance. This device should be used by the patient at all times except when eating and brushing.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz dentistry faculty
Full name of responsible person
ahmad behroozian
Street address
Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, IRAN
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tabriz
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Postal code
5166614711
Phone
+98 41 3335 5965
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info@dentistryfac.tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Mohammad Samiei
Street address
Central Building of Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3177 1041
Email
dabirkhanecent@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
dr.ahmad behroozian
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
dr.ahmadbehroozian
Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

mahsazali

Position

masters student

Latest degree

Bachelor

Other areas of specialty/work

Speech therapy

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Province

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Postal code

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Phone

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Study protocol

When the data will become available and for how long

from1 401

To whom data/document is available

clinicians and therapists

Under which criteria data/document could be used

Data analysis is not allowed, for viewing only.

From where data/document is obtainable

m.mahsa.zali@gmail.com

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

send mail

Comments