

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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 assignments 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, Goltasht Ave, Tabriz, IRAN

#### City

tabriz

#### Province

East Azarbaijan

#### Postal code

5166614711

#### Phone

+98 41 3335 5965

#### Email

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, Goltasht 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

Faculty of Dentistry, Tabriz University of Medical Sciences, Goltasht Ave, Tabriz, IRAN

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#### Province

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#### Phone

+98 41 3335 5965

#### Email

ahmadbehroozian@yahoo.com

## 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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No. 26, aval ordibehesht alley, 22bahman Ave., Tabriz

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**Province**

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**Postal code**

5178647435

**Phone**

+98 41 3442 7984

**Email**

m.mahsa.zali@gmail.com

**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**