

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

the comparison of the clinical and muscular effects of traditional twin block and clear twin block: a randomized clinical trial

Protocol summary

Study aim

The comparison of the clinical effects of traditional and clear twin block

Design

clinical trial with two groups and the 60 patients, randomized with SNOSE method.

Settings and conduct

In this randomized clinical trial, the clinical effects of traditional twin block and clear twin block will be compared. Sixty patients who need growth modification treatment will be selected and randomly divided into two groups. At the end of the treatment skeletal and dental changes and muscular functions will be examined. The mechanism of clear twin block is the same as traditional twin block but acrylic material is replaced with thermoplastic sheets. Electromyography will be done to measure the muscular function and cephalometric analysis will be done for measurement of skeletal and dental changes and all data will be recorded in the check list. Furthermore a part of treatment results will be checked six months later. We will use spss ver 24 for data analysis. paired t- test will be used for before-after comparison and independent t test will be used for the comparison between the groups.

Participants/Inclusion and exclusion criteria

the patients should be in the growth spurt stage. the willingness of the patient and parents for the treatment skeletal class II div 1 the presence of suitable teeth for the retention of the appliance informed consent of the patient

Intervention groups

traditional twin block clear twin block

Main outcome variables

improvement in jaw relationship improvement in muscle function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170723035238N3**
Registration date: **2021-12-11, 1400/09/20**
Registration timing: **retrospective**

Last update: **2021-12-11, 1400/09/20**

Update count: **0**

Registration date

2021-12-11, 1400/09/20

Registrant information

Name

ahmad behroozian

Name of organization / entity

tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 33379351

Email address

behrooziana@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-25, 1400/08/03

Expected recruitment end date

2021-11-24, 1400/09/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

the comparison of the clinical and muscular effects of traditional twin block and clear twin block: a randomized

clinical trial

Public title

the comparison of the effects of traditional twin block and clear twin block

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

the patients should be in the growth spurt stage. skeletal class II div 1 informed consent of the patient the willingness of the patient and parents for the treatment the presence of suitable teeth for the retention of the appliance

Exclusion criteria:

lack of the cooperation of the patient in follow up recalls lack of oral hygiene lack of the cooperation of the patient in restoration of decayed teeth before beginning of orthodontic treatment

Age

From **11 years** old to **14 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

numbered, sealed, opaque envelope (SNOSE) in this allocation system the researchers use mate envelopes. the number of the envelopes is equal with the number of the patients in each group. then the envelopes are gathered in the box .for each patients one envelope will be selected randomly and the group (case or control) will be selected in this way.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

•Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz / Azadi st. / gulgasht st. / Central building of

Tabriz medical university

City

Tabriz

Province

East Azarbaijan

Postal code

5163916737

Approval date

2021-10-25, 1400/08/03

Ethics committee reference number

IR.TBZMED.REC.1400.730

Health conditions studied

1

Description of health condition studied

skeletal class II

ICD-10 code

M26.212

ICD-10 code description

Malocclusion, Angle's class II

Primary outcomes

1

Description

Correction of jaw relationship

Timepoint

6 months later

Method of measurement

cephalometry

2

Description

improvement in muscle function

Timepoint

1, 3 and 6 month later

Method of measurement

surface electromyography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: clear twin block

Category

Treatment - Devices

2

Description

Intervention group: traditional twin block

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentiistry faculty / Tabriz University of Medical Science / Gulgashst st. / Azadi st. / Tabriz

Full name of responsible person

Ahmad Behroozian

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Recruitment center

Name of recruitment center

office, Dr Ahmad Behroozian

Full name of responsible person

Ahmad Behroozian

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unit b, floor 3, eskan medical building, Abresan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

Ahmad Behroozian

Position

Assistant professor

Latest degree

Specialist

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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Position

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

the results of the study we be published in the scientific journals .

When the data will become available and for how long

2022-5-10

To whom data/document is available

open access

Under which criteria data/document could be used

for researchers in medical sciences

From where data/document is obtainable

one can find the data in the journal which the article will be published in it.

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

the access will be according to the policy of the journal which the article will be published in it

Comments