Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

clinical trial

Public title
the comparison of the effects of traditional twin block andclear 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 thee 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 envelops 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
۵۱۶۳۹۱۶۷۳۷
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
cephalometery

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 / Gulgasht st. / Azadi st. / Tabriz

Full name of responsible person
Ahmad Behroozian

Street address
Tabriz / Azadi st. / gulgasht st. / Central building of Tabriz medical university

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3334 0310

Fax
+98 41 3334 6977

Email
ahmadbehroozian@gmail.com

2

Recruitment center

Name of recruitment center
office, Dr Ahmad Behroozian

Full name of responsible person
Ahmad Behroozian

Street address
unit b,floor 3, eskan medical building, Abresan

City
Tabriz

Province
East Azarbaijan

Postal code
۵۱۶۳۹۱۶۷۳۷

Phone
+98 41 3336 2055

Email
ahmadbehroozian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Ahmad Behroozian

Street address
Tabriz / Azadi st. / gulgasht st. / Central building of Tabriz medical university

City
Tabriz

Province
East Azarbaijan

Postal code
5166614711

Phone
+98 41 3334 0310

Email
ahmadbehroozian@gmail.com

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

Street address
Tabriz / Azadi st. / gulgasht st. / Central building of Tabriz medical university

City
Tabriz

Province
East Azarbaijan

Postal code
۵۱۶۳۹۱۶۷۳۷

Phone
004133347635

Email
ahmadbehroozian@gmail.com

Web page address
http://www.drbehroozian.com

Person responsible for scientific 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
Street address
Tabriz / Azadi st. / gulgasht st. / Central building of Tabriz medical university
City
Tabriz
Province
East Azarbaijan
Postal code
۵۱۶۳۹۱۶۷۳۷
Phone
+98 41 3334 7635
Email
ahmadbehroozian@gmail.com
Web page address
http://www.drbehroozian.com

Person responsible for updating data

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
Street address
Tabriz / Azadi st. / gulgasht st. / Central building of Tabriz medical university
City
Tabriz
Province
East Azarbaijan
Postal code
۵۱۶۳۹۱۶۷۳۷
Phone
+98 41 3334 7635
Email
ahmadbehroozian@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
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