Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of intermaxillary fixation’s impact on skeletal relapse after mandibular advancement surgery:A randomized clinical trial

Protocol summary

Study aim
comparing a mount of relapse after mandibular advancement surgery with elastic therapy and mandibular advancement surgery with inetermaxillary fixation

Design
this is a randomized clinical trial.two groups of skeletal class II patient would participate in the study. both groups would require 5 -10 mm mandibular advancement surgery. all patients would have operated with same surgical technique by same surgeon. After the surgery; one group of patients would have inter maxillary fixation for 4-6 weeks mean while the other group would have elastic therapy. The sample size would be 28 patients in each group.

Settings and conduct
patients would be operated in Talaghani hospital. All patients undergo BSSO surgery with Dal pont's technique. After surgery, the first group will undergo elastic therapy and the other group will have IMF .this study could not be blinded because patients would realized post operative treatment modality (elastic therapy vs Inetrmaxillary fixation)

Participants/Inclusion and exclusion criteria
inclusion criteria: 1.patients with postpubertal skeletal maturity 2.patients with completed presurgical orthodontic treatment 3.patients with skeletal class II requiring mandibular advancement surgery. exclusion criteria: 1. patients who require synchronized maxillary orthognatic surgery 2. patients with poorly controlled systematic disease such as diabetes melitus, etc.

Intervention groups
in this study no control group would be utilized;. two groups of skeletal class II patient would participate in the study. both groups would require 5 -10 mm mandibular advancement orthognathic surgery. All patients would have operated with same surgical technique by same surgeon. After the surgery; one group of patients would have inter maxillary fixation for 4-6 weeks mean while the other group would have elastic therapy.

Main outcome variables
comparison of cephalometric points

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191126045510N1**
Registration date: **2020-01-26, 1398/11/06**
Registration timing: **prospective**

Last update: **2020-01-26, 1398/11/06**
Update count: **0**

Registration date
2020-01-26, 1398/11/06

Registrant information

Name
Arash Sarafzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2303 1316

Email address
a.sarafzadeh@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-19, 1398/11/30

Expected recruitment end date
2020-12-29, 1399/10/09

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of intermaxillary fixation’s impact on skeletal relapse after mandibular advancement surgery:A randomized clinical trial

Public title

Evaluation of inter maxillary fixation’s impact on skeletal relapse after mandibular advancement surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with skeletal class II requiring mandibular advancement surgery (5 -10 mm advancement) patients with completed presurgical orthodontic treatment patients with postpubertal skeletal maturity

Exclusion criteria:

patients who had synchronized maxillary orthognatic surgery patients with poorly controlled systematic disease such as diabetes melitus, etc. patients with previous anti resorptive drug such bisposphonates, etc.

Age

From **17 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

We select patients who have undergone preoperative orthodontics and they require 5-10 mm advancment mandibular orthodontic surgery. All samples are coded and arranged. After coding the samples we use a random number table to divide all samples in two groups. by moving in a row in table only the numbers smaller than the total number of samples are selected. Each samples with the same numbers is selected and is placed in the first group. we would continue this process until the half of samples is allocated in the first group. all other samples is assigned to the second group. The first group was selected as code one and the second group as number two. finally an other random number is selected in the table. if the number is odd the first group would be treated with intermaxillary fixation and if the number is even the second group would be treated as such. The non selected group would be treated with elastic therapy respectively.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran National committee for ethics in biomedical research

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

tehran

Province

Tehran

Postal code

1983963113

Approval date

2019-07-03, 1398/04/12

Ethics committee reference number

IR.SBMU.DRC.REC.1398.101

Health conditions studied

1

Description of health condition studied

subjects in this study were patients with mandibular hypoplasia.

ICD-10 code

M26.04

ICD-10 code description

Mandibular hypoplasia

Primary outcomes

1

Description

Me- y axis: It is the distance between Menthon and Y-Axis on cephalogram.

Timepoint

It is evaluated in three time periods: before intervention (T0), one week after intervention (T1) and one year after intervention (T2).

Method of measurement

it would be evaluated by standard metallic ruler based on distance between cephalometric reference points on lateral cephalograms.

2

Description

B-Y axis: It is the distance between B point and Y-Axis on cephalogram

Timepoint
It is evaluated in three time periods: before intervention (T0), one week after intervention (T1) and one year after intervention (T2).
Method of measurement
it would be evaluated by standard metallic ruler based on distance between cephalometric reference points on lateral cephalograms.

3

Description
Pog -Y axis: It is the distance between Pog and Y-Axis on cephalom
Timepoint
It is evaluated in three time periods: before intervention (T0), one week after intervention (T1) and one year after intervention (T2).
Method of measurement
it would be evaluated by standard metallic ruler based on distance between cephalometric reference points on lateral cephalograms.

4

Description
Me- X axis: It is the distance between Menthon and X-Axis on cephalogram.
Timepoint
It is evaluated in three time periods: before intervention (T0), one week after intervention (T1) and one year after intervention (T2).
Method of measurement
it would be evaluated by standard metallic ruler based on distance between cephalometric reference points on lateral cephalograms.

5

Description
B-X axis: It is the distance between B point and X-Axis on cephalogram
Timepoint
It is evaluated in three time periods: before intervention (T0), one week after intervention (T1) and one year after intervention (T2).
Method of measurement
it would be evaluated by standard metallic ruler based on distance between cephalometric reference points on lateral cephalograms.

6

Description
Pog -X axis: It is the distance between Pog and X-Axis on cephalogram
Timepoint
It is evaluated in three time periods: before intervention (T0), one week after intervention (T1) and one year after intervention (T2).
Method of measurement
it would be evaluated by standard metallic ruler based on distance between cephalometric reference points on lateral cephalograms.

Secondary outcomes

empty

Intervention groups

1

Description
control group: skeletal class II patents with 5 -10 mm skeletal discrepancy undergo mandibular advancement orthognathic surgery with bilateral sagittal split osteotomy with Dalpont's technique. after ward they would receive elastic therapy with medium force class II (4.5 Oz). in each side of patients mouth medium force elastic would be inserted from mandiular premolars to maxillary canins and from mandibular first molars to maxillary second premolars.
Category
Treatment - Other

2

Description
Intervention group: Intervention group: skeletal class II patents with 5 -10 mm skeletal discrepancy undergo mandibular advancement orthognathic surgery with bilateral sagittal split osteotomy with Dalpont's technique. after ward they would receive inter maxillary fixation for 6 weeks with 28 guages wire brackets.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Educational Hospital
Full name of responsible person
Reza Tabrizi
Street address
Taleghani Educational Hospital, Arabi St.Yemen St, Chamran High Way, Tehran, Iran
City
tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2243 2560
Email
taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

City
tehran

Province
Tehran

Postal code
1983963113

Phone
+98 21 2243 9770

Email
Intl_office@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Shahid beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
reza tabrizi

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Oral and maxillofacial surgery

Street address
School of Dentistry, Daneshjoo Blvd, Evin, Shahid Chamran Highway

City
tehran

Province
Tehran

Postal code
1983963113

Phone
+98 21 2240 3075

Email
rtabrizi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Reza Tabrizi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Oral and maxillofacial surgery

Street address
School of Dentistry, Daneshjoo Blvd, Evin, Shahid Chamran Highway

City
Tehran

Province
Tehran

Postal code
1983969411

Phone
+98 21 2217 5350

Email
rtabrizi@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Reza Tabrizi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Oral and maxillofacial surgery

Street address
School of Dentistry, Daneshjoo Blvd, Evin, Shahid Chamran Highway

City
Tehran

Province
Tehran

Postal code
1983969411

Phone
+98 21 2217 5350

Email
rtabrizi@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

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

Title and more details about the data/document

all cephalometric analysis data would be available for other researchers if needed.

When the data will become available and for how long

starting 6 mounths after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

there is no limitation for analysis of data

From where data/document is obtainable

Contact with Tabmed@gmail.com or +989124473239

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

All verified researchers could receive cephalometric analysis after ascertainment of privacy of patients. they could receive data with an email.

Comments