

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 amount 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 Inetmaxillary 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 orthognathic 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

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Iran (Islamic Republic of)

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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 advancement 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

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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

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Taleghani Educational Hospital, Arabi St.Yemen St, Chamran High Way, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

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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 months 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