Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Quasi experimental study of accuracy comparison of thick wafer with standard wafer, in transferring of sagittal position of maxilla during lefort 1 osteotomy in patients with skeletal discrepancy of the jaws

Protocol summary

Summary

The purposes of this study are efficiency evaluation of thick wafer in comparison with standard wafer on assessment of maxillary sagittal position during orthognathic surgery. This is a single arm Quasi-experimental trial study, which will be performed on 9 patients with skeletal discrepancy of the jaws, class 2 and 3, who would be referred to oral and maxillofacial surgery clinic of Shariati hospital of Tehran. The inclusion criteria is skeletal discrepancy of the jaws, class 2 or 3, without previous history of orthognathic surgery. The exclusion criteria is the patients who are unwilling to sign the written consent for. In each case, mandibular and maxillary casts would be provided and fixed to the arthiculator. Then model surgery of the patient will begin and maxillary cast separates from the arthiculator base and will be fixed to the arthiculator in 2 mm more anterior than the primary position (0 position). Then maxillary cast will be separated from arthiculator, and fixed to it in 1 mm more anterior than 0 position (a-1 position). Now, a standard wafer and a thick wafer with 5 mm thickness, would be provided. This procedure would be replicated in 2 mm and 3 mm more anterior than 0 position (a-2 position and a-3 position). During the operation, horizontal osteotomy line will be marked on maxillary bone with a bur and a vertical line would be drown on the bone at molar area. Now, lefort 1 osteotomy and maxillary down fracture will be performed. At this time maxilla would be repositioned with the standard wafer for a-1 position, as two segments of the maxilla interconnect at the osteotomy line. Then amount of displacement of vertical line on down fractured maxillary segment from vertical line on the base of the maxilla would be measured. Now, thick wafer for a-1 position will be placed and the same measurement will be performed . This procedure would be repeated with provided wafers in a-2 and a-3 positions, and finally data from this study would be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015032521539N1**
Registration date: **2015-05-21, 1394/02/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-05-21, 1394/02/31

Registrant information

Name

Aref Darvishi

Name of organization / entity

Tehran University of Medical Sciences, Faculty of Dentistry

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Self funded

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Quasi experimental study of accuracy comparison of thick wafer with standard wafer, in transferring of sagittal position of maxilla during lefort 1 osteotomy in patients with skeletal discrepancy of the jaws

Public title

Efficiency evaluation of thick wafer in assessment of maxillary position in orthognathic surgery

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: the patients with skeletal discrepancy of the jaws, class 2 or 3, without previous orthognathic surgery Exclusion criteria: the patients who are unwilling to sign the written consent for

Age

From **19 years** old to **27 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **9**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd., Tehran

City

Tehran

Postal code

Approval date

2014-10-01, 1393/07/09

Ethics committee reference number

8911250001

Health conditions studied

1

Description of health condition studied

Skeletal discrepancy of the jaw

ICD-10 code

Q65-Q79

ICD-10 code description

Congenital malformations and deformations of the musculoskeletal system

Primary outcomes

1

Description

Amount of displacement of mobilized segment of the maxilla

Timepoint

During the operation of the patient

Method of measurement

based on millimeter

Secondary outcomes

empty

Intervention groups

1

Description

During the operation, after lefort 1 osteotomy, with use of the standard wafer for a-1position, position of the maxillary mobilized segment will be marked on the base of the maxilla, and then this marking will be replicated with thick wafer for a-1 position, and finally distance between these two points will be measured. This procedure will be repeated with provided thick and standard wafers for a-2 and a-3 position. Finally 3 measures will be gained from each patient.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of oral and maxillofacial surgery of Shariati hospital

Full name of responsible person

Aref Darvishi, resident in oral and maxillafacial surgery

Street address
Clinic of oral and maxillofacial surgery, Shariati hospital of Tehran,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Masud Yunesian
Street address
Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd., Tehran
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Vice chancellor for research, Tehran University of Medical Sciences, faculty of dentistry
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty