

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 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 articulator. Then model surgery of the patient will begin and maxillary cast separates from the articulator base and will be fixed to the articulator in 2 mm more anterior than the primary position (0 position). Then maxillary cast will be separated from articulator, 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 drawn 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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Email address

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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-1 position, 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

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

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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

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****Name of organization / entity**

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

Full name of responsible person

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

Position

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Full name of responsible person

Farnush Mohammadi

Position

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Position

Resident in oral and maxillofacial surgery

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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