

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Dimensional changes of periimplant soft and hard tissues after immediate flapless implantation in posterior sites of the jaws, with or without filling the gap around implant; A randomised clinical trial

Protocol summary

Study aim

Evaluation of hard and soft tissue dimensional changes after immediate flapless implantation with or without filling the gap around implant by bone substitute material

Design

Two arm parallel group randomized clinical trial with blinded patients. In the control group the gap around implant will remain empty, but in the test group the gap will be filled by xenograft bone substitute material. Sample size will be 66 implants. Thirty three implants will be allocated to each group by blocked randomization with random block size.

Settings and conduct

Surgery will be done in a private clinic in Tehran. Cone Beam Computed Tomography (CBCT) and Intra-oral scans will be prescribed before and 6 months after surgery to evaluate tissue dimensional changes. Patients and data analyst will be blinded; however, it will not be possible to blind the surgeon and the outcome assessor.

Participants/Inclusion and exclusion criteria

Presence of at least 1 molar tooth to be extracted and replaced by implant; Presence of at least 3 millimeters bone apical to the tooth

Intervention groups

Molar teeth will be extracted atraumatically and replaced by implants without raising the flap. The gap around implants will be filled by xenograft in the test group and will remain empty in the control group.

Main outcome variables

Alveolar bone width and height changes; Soft tissue thickness and height changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190626044018N1**

Registration date: **2020-01-11, 1398/10/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-11, 1398/10/21**

Update count: **0**

Registration date

2020-01-11, 1398/10/21

Registrant information

Name

علی Ali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2254 3982

Email address

homayouni.dmd@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-11, 1398/08/20

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Dimensional changes of periimplant soft and hard tissues after immediate flapless implantation in posterior sites of

the jaws, with or without filling the gap around implant; A randomised clinical trial

Public title
Effectiveness of filling the gap around immediate implants

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Presence of at least 1 molar tooth to be extracted and replaced by implant Presence of at least 3mm bone apical to the tooth
Exclusion criteria:
 Uncontrolled Periodontitis Uncontrolled Diabetes Mellitus Patients smoking more than 10 cigarettes per day Presence of acute infection around the candidate tooth

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Blocked randomization with randomly selected block sizes Randomization unit: Individual Randomization sequence generation: Online www.graphpad.com/quickcalcs/randomize1 Allocation concealment: Type of intervention will be written on a paper and secured in a sealed enveloped for each patient. During the surgery and after implant placement the envelope will be opened and the type of intervention will be revealed.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, blinding the surgeon and the one who measures the outcomes will not be possible; but, the patient and the one who analyses the data will be blinded.

Placebo
Not used

Assignment
Parallel

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
 School of Dentistry, North Kargar St.
City
 Tehran
Province
 Tehran
Postal code
 ۱۴۳۹۹۵۵۹۹۱
Approval date
 2019-10-22, 1398/07/30
Ethics committee reference number
 IR.TUMS.VCR.REC.1398.636

Health conditions studied

1

Description of health condition studied
 Dimensional changes of hard and soft tissues after tooth extraction
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
 Alveolar bone width changes
Timepoint
 Preoperative and 6-month postoperative
Method of measurement
 Cone Beam Computed Tomography

Secondary outcomes

1

Description
 Alveolar bone height changes
Timepoint
 Preoperative and 6-month postoperative
Method of measurement
 Cone Beam Computed Tomography

2

Description
 Soft tissue height changes
Timepoint
 Preoperative and 6-month postoperative
Method of measurement
 Intra-oral scanner

3

Description

Soft tissue thickness changes

Timepoint

Preoperative and 6-month postoperative

Method of measurement

Intra-oral scanner

Intervention groups

1

Description

Intervention group: After chlorhexidine mouthwash prescription and anesthesia with lidocaine molar teeth will be sectioned into crown and roots by high-speed bur and extracted by periosteal and forceps atraumatically. Drilling will be performed sequentially into the interradicular bone without raising the flap. Implants will be inserted 1mm subcrestally. The gap around implants will be filled by xenograft. Healing abutments will be inserted and the socket will be sutured by a nonresorbable material.

Category

Treatment - Surgery

2

Description

Control group: Intervention group: After chlorhexidine mouthwash prescription and anesthesia with lidocaine molar teeth will be sectioned into crown and roots by high-speed bur and extracted by periosteal and forceps atraumatically. Drilling will be performed sequentially into the interradicular bone without raising the flap. Implants will be inserted 1mm subcrestally. The gap around implants will be left empty. Healing abutments will be inserted the socket will be sutured by a nonresorbable material.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Private Clinic

Full name of responsible person

Ali Homayouni

Street address

No. 163, Bahar-e-shiraz St.

City

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+98 21 8830 8630

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homayouni.dmd@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Amirreza Rokn

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1439955991

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arrokn@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Ali Homayouni

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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No. 29, East Akhlaghi St., Kolahdouz Ave.

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

Not applicable

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The whole IPD, study protocol, informed consent form and trial results will be published in the post-graduate thesis print.

When the data will become available and for how long

Unlimited access to the data since dissertation publish.

To whom data/document is available

There is no limit for IPD request

Under which criteria data/document could be used

There is no specific requirement for researchers who need IPD

From where data/document is obtainable

IPD requests should be sent by e-mail to Dr.Ali Homayouni: homayouni.dmd@gmail.com

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

After sending the IPD request including the reason why you need the IPD, you will be qualified and the data will be sent within a month.

Comments