Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Dimensional changes of periimplant soft and hard tissues after immediate flapless implantition 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 remained 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 analyser 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 an will remained empty in the control group.

Main outcome variables
Alveolar bone width and height changes; Soft tissue tickness 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 implantition 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 periotome 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 periotome 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
Tehran
Province
Tehran
Postal code
۱۹۳۹۸۴۴۷۳۱
Phone
+98 21 8830 8630
Email
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
Street address
Dentistry School, North Kargar St.
City
Tehran
Province
Tehran
Postal code
1439955991
Phone
+98 21 8801 5950
Email
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
Street address
No. 29, East Akhlaghi St., Kolahdouz Ave.
City
Tehran
Province
Tehran

Postal code
1939844731
Phone
+98 21 2254 3982
Email
homayouni.dmd@gmail.com

Person responsible for scientific 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
Street address
No. 29, East Akhlaghi St., Kolahdouz Ave.
City
Tehran
Province
Tehran
Postal code
1939844731
Phone
+98 21 2254 3982
Fax
Email
homayouni.dmd@gmail.com

Person responsible for updating data

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
Street address
No. 29, East Akhlaghi St., Kolahdouz Ave.
City
Tehran
Province
Tehran
Postal code
1939844731
Phone
+98 21 2254 3982
Email
homayouni.dmd@gmail.com

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