Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The evaluation and comparin gthe clinical and radiographic immediate implant in mandibular molar teeth with and without grafting materials

Protocol summary

Study aim
Evaluating and comparing the clinical and radiographic aspects of immediate implant in mandibular teeth with and without allograft

Design
Simple randomized 2-3 phase clinical trial with parallel groups in a single-blind fashion on 30 patients.

Settings and conduct
The hospital of the Mashhad University of Medical Sciences

Participants/Inclusion and exclusion criteria
Including criteria: Patients in the need of implant surgery. Patients with at least 2 mm width of keratinized gum across the hopeless tooth. Patients with at least 2 mm of the buccal implant to the internal side of the buccal bone distance. Excluding criteria: Patients with periodontitis in the hopeless region of the tooth. Patients that after extracting the hopeless tooth will experience dehiscence and fenestration in the extraction site.

Intervention groups
Intervention group: Implanting will be performed by local anesthesia. The teeth extraction is being performed by atraumatic and by removing the roots first to maintain the bony filament. After extraction, the best region for implantation is chosen. According to the implant manufacturer, the place would be drilled and then, the implant will be inserted and closed to the area with healing. At last, the grafting material would be added. Control group: Implanting will be performed by local anesthesia. The teeth extraction is being performed by atraumatic and by removing the roots first to maintain the bony filament. After extraction, the best region for implantation is chosen. According to the implant manufacturer, the place would be drilled and then, the implant will be inserted and closed to the area with healing. At last, no material would be added.

Main outcome variables
Bone degeneration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220108053669N2**
Registration date: **2022-04-22, 1401/02/02**
Registration timing: **prospective**

Last update: **2022-04-22, 1401/02/02**
Update count: **0**

Registration date
2022-04-22, 1401/02/02

Registrant information

Name
Peyman Esmaeili Fard Barzegar

Name of organization / entity
Lorestan University

Country
Iran (Islamic Republic of)

Phone
+98 21 4411 3043

Email address
esmaeili.pe@fv.lu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-22, 1401/04/01

Expected recruitment end date
2022-09-23, 1401/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The evaluation and comparin gthe clinical and radiographic immediate implant in mandibular molar teeth with and without grafting materials

Public title
The evaluation of immediate implant in molar teeth
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The patients who need implant surgery The patients with hopeless peritooth keratinized gum width of more than 2 mm. The patients whose implant buccal distance to the internal surface of buccal bone is more than 2 mm.
Exclusion criteria:
The patients who are suffering from periodontitis in the hopeless region. the patients who after extracting the hopeless tooth suffered from dehiscence or fenestration in extraction region
Age
From **22 years** old to **58 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomized, in which all patients who were referred to this hospital and had the including criteria, were completely randomly entered and examined statistically until the number reached the desired patients.
Blinding (investigator's opinion)
Single blinded
Blinding description
The patients in both groups were unaware of the kind of material used (Single-blind), but the nurse who administered the drug and the scientists were aware of the contained drug.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad University of Medical Sciences
Street address
Knowledge and Health City - In the end of Shahid Fakouri Blvd (In the front of Fakouri 94)
City
Mashhad
Province
Razavi Khorasan
Postal code
99191-91778
Approval date
2019-10-05, 1398/07/13
Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1399.068

Health conditions studied

1

Description of health condition studied
tooth Implant
ICD-10 code
Z96.5
ICD-10 code description
Presence of tooth-root and mandibular implants

Primary outcomes

1

Description
Pocket depth
Timepoint
After implanting, 3 months after surgery and 3 months after loading.
Method of measurement
It is evaluated clinically

2

Description
Bleeding on probing (BOP)
Timepoint
After implanting, 3 months after surgery and 3 months after loading.
Method of measurement
It is evaluated clinically.

3

Description
The distance between bone and border of implant
Timepoint
After implanting, 3 months after surgery and 3 months after loading.
Method of measurement
With the help of radiograph.

4

Description
The thickness of keratinized gum.

Timepoint
After implanting, 3 months after surgery and 3 months after loading.
Method of measurement
Clinically

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Implanting will be performed by local anesthesia. The teeth extraction is being performed by atraumatic and by removing the roots first to maintain the bony filament. After extraction, the best region for implantation is chosen. According to the implant manufacturer, the place would be drilled and then, the implant will be inserted and closed to the area with healing. At last, the grafting material would be added.
Category
Treatment - Drugs

2

Description
Control group: Implanting will be performed by local anesthesia. The teeth extraction is being performed by atraumatic and by removing the roots first to maintain the bony filament. After extraction, the best region for implantation is chose. According to the implant manufacturer, the place would be drilled and then, the implant will be inserted and closed to the area with healing. At last, no material would be added.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad University of Medical Sciences hospital
Full name of responsible person
Dr. Nahid Nasrabadi
Street address
7GJP+VPQ, Daneshgah street, Mashhad, Khorassan Razavi, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3841 4565
Email
nasrabadi.nahid@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Nahid Nasrabadi
Street address
Daneshgah street, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3805 7100
Email
nasrabadi.nahid@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Nahid Nasrabadi
Position
Assistant professor of periodontology
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Daneshgah street, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone

+98 51 3806 7100

Email

nasrabadi.nahid@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Nahid Nasrabadi

Position

Assistant professor of periodontology

Latest degree

Specialist

Other areas of specialty/work

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City

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Phone

+98 51 3806 7100

Email

nasrabadi.nahid@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Nahid Nasrabadi

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Assistant professor of periodontology

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Email

nasrabadi.nahid@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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