Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Gelfoam And Bone Inducing Material in Preventing Marginal Bone Loss in Immediate Implant Insertion of Anterior Teeth

Protocol summary

Study aim
Comparison of gelfoam and bone inducing material in preventing marginal bone loss in immediate implant insertion of anterior teeth after 3,6 and 9 mounths.

Design
In this clinical trial 60 patients having the inclusion criteria divided randomly in two groups using hexagonal blocks. After placement of the anterior immediate implant, the gap will filled with gelfoam in the intervention group and with bone material in the control group. Both groups will be followd 3,6 and 9 month after placement.

Settings and conduct
patients who are candidate for immediate implantation who will refer to Semnan School of Dentistry during the study period will be enrolled into the trial. Tooth will be extracted flaplessly for all patients. The implant surgery will be done and the implant will be inserted. After the procedure periapical radiographic imaging will be taken. Patients will be examined by an oral and maxillofacial surgeon and a prosthodontist.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients who are candidate for immediate implantation with at least 2 mm attached gingiva width and no sign of fistula or infection will be enrolled into the trial.Exclusion criteria: Systemic disease; addiction; bruxism;using special drugs; bone graft candidate; presence of dehiscence and fenestration and insufficient buccal bone(minimum 1mm buccal bone is necessary.)

Intervention groups
Intervention group: placement of immediate implant and using gelfoam for filling the gap.

Main outcome variables
Buccal table bone resorption

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190830044644N1**
Registration date: **2019-11-10, 1398/08/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-10, 1398/08/19**
Update count: **0**

Registration date
2019-11-10, 1398/08/19

Registrant information

Name
Yasaman Sahraeeyan

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-23, 1398/08/01

Expected recruitment end date
2020-01-21, 1398/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Gelfoam And Bone Inducing Material in Preventing Marginal Bone Loss in Immediate Implant Insertion of Anterior Teeth

Public title
Gelfoam And Bone Inducing Material in Preventing Marginal Bone Loss in Immediate Implant Insertion
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients who candidates for immediate implant at least 2 mm attached gingiva width no sign of fistula or infection
Exclusion criteria:
systemic disease addiction bruxism using special drugs bone graft candidate presence of dehiscence and fenestration insufficient buccal bone
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients divided randomly in two groups by using hexagonal blocks.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Semnan University of Medical Sciences
Street address
Vice chancellor for research, Semnan University of Medical Sciences building, Basij Blvd
City
Semnan
Province
Semnan
Postal code
35198-99951
Approval date
2019-05-21, 1398/02/31
Ethics committee reference number
IR.SEMUMS.REC.1398.098

Health conditions studied

1

Description of health condition studied
Comparison of alveolar bone resorption while using gelfoam and bone material in dental socket.
ICD-10 code
Z96.5
ICD-10 code description
Presence of tooth-root and mandibular implants

Primary outcomes

1

Description
Amount of alveolar bone resorbtion
Timepoint
3,6 and 9 months after implant insertion
Method of measurement
Priapical Radiographic imaging

Secondary outcomes

empty

Intervention groups

1

Description
Control group: After placement of immediate implant in this group, bone material is used to fill the gap between implant and the buccal bone.
Category
Treatment - Other

2

Description
Intervention group: After placement of immediate implant in this group, Gelfoam is used to fill the gap between implant and the buccal bone.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Semnan dental university
Full name of responsible person
Anahita Shahi
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Sponsors / Funding sources

1

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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
Semnan 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
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Semnan University of Medical Sciences
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Anahita Shahi
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Assistant professor
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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