Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The clinical , histological and histomorphometrical comparison of the effect of decalcified friezed – dried bone allogenic graft with platelet rich plasma for alveolar ridge preservation post extraction.

Protocol summary

Summary

Alveolar ridge atrophy is one of the undesirable outcomes of tooth loss which cause some functional and esthetic problems. The clinician should use ridge reconstruction and bone augmentation prior to implant placement. Preservation of alveolar bone after tooth extraction minimize bone resorption and as technique implies preservation of the alveolar architecture and prevention of hard and soft-tissue collapse that minimize or eliminate the necessity for future augmentation procedures. this has been long studied but is still an unresolved problem. In this study we compare the success of edentulous ridge preservation with allograft bone material with or without platelet rich plasma. This study will include 16 mandibular dental sockets of patients referred to period ontology and implant logy department of dental faculty regardless of age and gender. The patients are selected according to inclusion and exclusion criteria (smoking, pregnancy,...) and divide in two groups test and control. In this study we use Decalcified freeze dried Bone Allergenic graft(DFDBA) with platelet rich plasma from patient and resorbable collagen membrane for test group and Decalcified freeze dried Bone Allergenic graft and resorbable collagen membrane for Control group. Variables like: The degree of inflammation, The thickness of bone trabeculae, Bone–Biomaterial contact, The rate of bone formation, Number of vessels, The remaining biomaterials, clinical changes of Buccolingual and Epicoronal width of the ridge are assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201309231760N25**

Registration date: **2013-10-27, 1392/08/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-10-27, 1392/08/05

Registrant information

Name

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Name of organization / entity

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Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Expected recruitment start date

2013-07-06, 1392/04/15

Expected recruitment end date

2015-03-06, 1393/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The clinical , histological and histomorphometrical comparison of the effect of decalcified friezed – dried bone allogenic graft with platelet rich plasma for alveolar ridge preservation post extraction.

Public title
The clinical , histological and histomorphometrical comparison of the effect of decalcified friezed – dried bone allogenic graft with platelet rich plasma for alveolar ridge preservation post extraction.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: do not be restored with tooth in the lower jaw implants and requires applicants who have indicated remove Ridge preservation; they are healthy; available for follow up courses. Exclusion criteria: patients those who can not go under surgery; cigarette (for now); osteoden - dental infection, untreated gingivitis or periodontist active; patients with teeth ankylosed; overall sense of teeth; patients with diseases that affect the tissue repair; use denture after surgery.

Age
No age limit

Gender
Both

Phase
4

Groups that have been masked
No information

Sample size
Target sample size: **16**

Randomization (investigator's opinion)
Randomized

Randomization description

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
The ethics committee of Babol University of Medical sciences

Street address
Babol University of Medical sciences, Ganjafroz Avenue

City
Babol

Postal code

Approval date
2013-07-02, 1392/04/11

Ethics committee reference number
2726

Health conditions studied

1

Description of health condition studied
Atrophy of the alveolar ridge of the jaws

ICD-10 code
K08.2

ICD-10 code description
Atrophy of edentulous alveolar ridge

Primary outcomes

1

Description
Protection statement edentulous

Timepoint
2 weeks after suture and 3 months after implant insertion time

Method of measurement
Clinical

Secondary outcomes

1

Description
The thickness of bone trabeculae

Timepoint
2 weeks after suture and 3 months after implant insertion time

Method of measurement
View software measure SIS LS Starter

2

Description
The degree of inflammation

Timepoint
2 weeks after suture and 3 months after implant insertion time

Method of measurement
Counting the number of inflammatory cells in high power field

3

Description
Bone - Biomaterial

Timepoint
2 weeks after suture and 3 months after implant insertion time

Method of measurement
Observed in high power field microscopy

4

Description
The rate of bone formation
Timepoint
2 weeks after suture and 3 months after implant insertion time
Method of measurement
Calculating the area occupied by bone SIS LS Starter Software

5

Description
Number of vessels
Timepoint
2 weeks after suture and 3 months after implant insertion time
Method of measurement
Counting the number of vessels

6

Description
The remaining biomaterials
Timepoint
2 weeks after suture and 3 months after implant insertion time
Method of measurement
Calculating the area occupied by bone SIS LS Starter Software

7

Description
Clinical changes buccolingual ridge width
Timepoint
2 weeks after suture and 3 months after implant insertion time
Method of measurement
clinical

8

Description
Clinical changes Epicocoronal ridge
Timepoint
2 weeks after suture and 3 months after implant insertion time
Method of measurement
clinical

Intervention groups

1

Description
Intervention group: Decalcified freeze dried Bone Allergenic graft(DFDBA) 0.5cc made in Iranian tissue bank with platelet rich plasma from patient and resorbable collagen membrane
Category
Treatment - Drugs

2

Description
Control group: Decalcified freeze dried Bone Allogenicgraft(DFDBA) 0.5cc and resorbable collagen membrane(15.20mm)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental colleges of Babol
Full name of responsible person
Dr. I San Pouri
Street address
Dental colleges of Babol, Babol University of Medical Sciences, Ganjafroz Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology, Babol University of Medical Sciences
Full name of responsible person
Dr. Ali Bijani
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Vice Chancellor for Research and Technology, Babol University of Medical Sciences, Ganjafroz Avenue
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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 and Technology, Babol 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
Dental School, Babol
Full name of responsible person
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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