

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health
Research Center, Babol University of Medical
Sciences

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 Epicoronal 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 Allogenicraft(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

City

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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

Dr. I-San Pouri

Position

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Web page address**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