

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Histologic and Histomorphometric Evaluation of Natix Synthetic Biomaterial in Horizontal Alveolar Ridge Augmentation

Protocol summary

Summary

Alveolar ridge atrophy of the jaw's, which is a basic problem encountered in patients seeking implant treatments, makes the augmentation procedure necessary. Disadvantages of using autografts, such as discomfort due to second stage surgery for harvesting bone from donor site, and limited volume of bone (from intra oral source), have led to interesting focus on using bone substitute materials. Among these materials, Natix made of commercially pure titanium, which is resistant against resorption and has good clotting properties as an osteoconductive material, has been newly introduced to the market. Therefore the purpose of this study is the histologic and histomorphometric assessment of this biomaterial in horizontal augmentation of resorbed alveolar ridge. The main inclusion criteria: 1- Patients ranging from 30 to 50 years old 2- Healthy patients demanding implant treatment in posterior regions of mandibular alveolar ridge The main exclusion criteria: 1- Patients unable to maintain oral health status or not interested in maintaining oral health status 2- Patients having untreated active periodontal disease. Target sample size: Comprises 10 augmentation sites in patients having a minimum of one augmentation site Time for intervention in order to assess the material from a histologic and histomorphometric standpoint is 8 month after augmentation. The primary outcome measure is the assessment of Natix for horizontal augmentation of alveolar ridge in terms of histologic and histomorphometric analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903164106N1**

Registration date: **2010-10-26, 1389/08/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-10-26, 1389/08/04

Registrant information

Name

Javad Mehrani Sabet

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2246 7316

Email address

j.mehrani@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2010-03-06, 1388/12/15

Expected recruitment end date

2011-01-05, 1389/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Histologic and Histomorphometric Evaluation of Natix Synthetic Biomaterial in Horizontal Alveolar Ridge Augmentation

Public title

Histologic and Histomorphometric Evaluation of Natix Synthetic Biomaterial in Horizontal Alveolar Ridge

Augmentation

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: 1- Patients ranging from 30 to 50 years old 2- Patients demanding implant treatment in posterior regions of mandibular alveolar ridge 3- Sufficient vertical height of bone in posterior mandibular region with inadequate buccolingual width (width of less than 5 mm and minimum width of 2 mm) 4- Healthy patients 5- Minimum of one augmentation site for each patient requiring implant treatment. Exclusion criteria: 1- Patients having systemic conditions affecting healing such as: Uncontrolled Diabetes, Immune diseases, Systemic or local diseases of bone, history of Alcoholism, Patients taking Immunosuppressive or Anticoagulant medications 2- poor compliance 3- Patients having untreated active periodontal disease 4- Patients unable to maintain oral health status or not interested in maintaining oral health status.

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Babol University of Medical Sciences

Street address

Periodontic Department, Faculty of Dentistry, Medical University, Ganjafrooz Avenue

City

Babol

Postal code

4717647745

Approval date

empty

Ethics committee reference number

ژ.پ.166.30

Health conditions studied

1

Description of health condition studied

Histologic and histomorphometric analysis of horizontal alveolar ridge augmentation

ICD-10 code

K08

ICD-10 code description

Other disorders of teeth and supporting structures

Primary outcomes

1

Description

Histologic and Histomorphometric Evaluation of effect of Natix Synthetic Biomaterial in Horizontal Alveolar Ridge Augmentation

Timepoint

8 months after intervention

Method of measurement

Biopsy specimens are taken from the augmented site by Natix, and are stained with Hematoxilin & Eosin and parameters such as: 1-amount of inflammation 2- existence or inexistence of foreign body reaction (giant cells and granulomatous reactions) 3-Bone vitality (Existence or inexistence of osteocytes in lacunaes) 4- Thickness of bone trabecules 5-Way of contact between bone-biomaterial (existence or inexistence of connective tissue between bone fragments) are analysed

Secondary outcomes

empty

Intervention groups

1

Description

After reflection of a full-thickness flap for gaining access to the buccal bone of edentulous ridge, Natix biomaterial is mixed with blood and saline and then placed on the area of bone defect. Then the augmented area will be covered by Cytoplast resorbable membrane. Without any tension the flaps are tied together. 8 month after surgery, full thickness flaps are reflected for the purpose of implant surgery. Biopsy specimens in shape of a bone core are harvested from the area of implant insertion. Specimens are sent to laboratory for histologic and histomorphometric study.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol University of Medical Sciences, Faculty of Dentistry

Full name of responsible person

Dr Javad Mehrani Sabet

Street address

Periodontic Department, Faculty of Dentistry, Medical University, Ganjafrooz Avenue

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Babol University of Medical Sciences

Full name of responsible person

Dr Amrollah Mostafazadeh

Street address

Department of Periodontics, Faculty of dentistry, Medical University, Ganjafrooz avenue

City

Babol

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, 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

Babol University of Medical Sciences, Faculty of Dentistry

Full name of responsible person

Dr Javad Mehrani Sabet

Position

Post Graduate Student

Other areas of specialty/work

Street address

Department of Periodontics, Faculty of dentistry,

Medical University, Ganjafrooz avenue

City

Babol

Postal code

Phone

+98 11 1222 4032

Fax

Email

j.mehrani@mubabol.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Javad Mehrani Sabet

Position

Post Graduate Student

Other areas of specialty/work

Street address

Department of Periodontics, Faculty of dentistry, Medical University, Ganjafrooz avenue

City

Babol

Postal code

Phone

+98 11 1222 4032

Fax

Email

j.mehrani@mubabol.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Javad Mehrani Sabet

Position

Post Graduate Student

Other areas of specialty/work

Street address

Department of Periodontics, Faculty of dentistry, Medical University, Ganjafrooz avenue

City

Babol

Postal code

Phone

Fax

Email

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