

# 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*