

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Clinical and radiographic evaluation of chitosan particles in treatment of periodontal intra bony defect

#### Protocol summary

##### Study aim

Clinical and radiographic evaluation of chitosan particles in treatment of periodontal intra bony defect

##### Design

clinical trial - with two test and one control group -double blind - randomized

##### Settings and conduct

Surgeries are done in periodontology department of Babol dental faculty. Patients don't know that involve in which group. The flap is set to "full thickness" then scaling & root planning is performed. In test groups in three-wall bone lesions, chitosan is placed in low or high molecular weight. Chitosan powder is mixed with some serum and placed in the bone lesion. Then, in each group, place the "Cenomembrane" membrane on the lumbar lesion and suture.

##### Participants/Inclusion and exclusion criteria

The entry requirements were presence of 3-walled intrabony defects in buccal or lingual sides of upper or lower first or second premolar or molars. The exclusion criteria were suffering from any kind of systemic disorders; a need for prophylactic antibiotics to prevent bacterial endocarditis; taking any drugs interfering with periodontal wound healing; smokers; presence of any periodontal surgery contraindications; teeth with anatomical complications such as cervical enamel projections; bifurcation ridge; accessory canal and concavity; presence of hemiseptal bony defects; presence of caries in the root of teeth adjacent to the intrabony defect and last but not least uncooperative patients

##### Intervention groups

People are divided into 3 groups. First, the chitosan test was done by the Acros Inc with high molecular weight (MW800000-600000) in intrabony defects during flap. Second, the chitosan test was done by the Acros Inc with low molecular weight (MW300000-100000) and in the control group the flap surgery is only done. The groups are matched with sex and place of the lesions.

#### Main outcome variables

Clinical attachment level - Probing pocket depth - Radiographic Defect Depth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100427003813N8**

Registration date: **2018-06-29, 1397/04/08**

Registration timing: **retrospective**

Last update: **2018-06-29, 1397/04/08**

Update count: **0**

##### Registration date

2018-06-29, 1397/04/08

##### Registrant information

##### Name

Nilloofar Jenabian

##### Name of organization / entity

Dental Faculty of University of Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 1229 1408

##### Email address

n.jenabian@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-05-21, 1395/03/01

##### Expected recruitment end date

2016-06-19, 1395/03/30

##### Actual recruitment start date

2016-05-21, 1395/03/01  
**Actual recruitment end date**  
2016-06-30, 1395/04/10  
**Trial completion date**  
empty

**Scientific title**  
Clinical and radiographic evaluation of chitosan particles in treatment of periodontal intra bony defect

**Public title**  
the effect of chitosan in periodontal intra bony defect

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

The entry requirements were presence of 3-walled intrabony defects in buccal or lingual sides of upper or lower first or second premolar or molars. plaque index under 20 between 30 - 50 years old

**Exclusion criteria:**

systemic disease taking any drugs interfering with periodontal wound healing smokers presence of any periodontal surgery contraindications teeth with anatomical complications such as cervical enamel projections; bifurcation ridge; accessory canal and concavity presence of hemi septal bony defects presence of caries in the root of teeth adjacent to the intrabony defect

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

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **18**  
Actual sample size reached: **18**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
The randomization scheme was 1:1:1 (2cases groups and 1 control group). Randomization was stratified by clinical trial site. The unblinded trial statistician generated randomization sequences (block randomization with block size of eight) and the unblinded clinical trial staff assigned each participant to a treatment group.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Patients do not aware of treatment group which they included The evaluator is different from surger and she is blind.

**Placebo**  
Not used

**Assignment**

Parallel  
**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Babol univercity of medical science

**Street address**

Ganjafrooz Ave.

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717647745

**Approval date**

2016-06-15, 1395/03/26

**Ethics committee reference number**

MUBABOL.REC.1395.146

**Health conditions studied**

1

**Description of health condition studied**

Chronic periodontitis

**ICD-10 code**

K05.3

**ICD-10 code description**

Chronic periodontitis

**Primary outcomes**

1

**Description**

clinical attachment level

**Timepoint**

at the begining of study and immediately before surgery, 6 and 12 months after sergury

**Method of measurement**

with periodontal probe

2

**Description**

probing depth

**Timepoint**

at the begining of study and immediately before surgery, 6 and 12 months after sergury

**Method of measurement**

with perodontal probe

### 3

#### **Description**

Radiographic Defect Depth

#### **Timepoint**

at the beginning of study and immediately before surgery, 6 and 12 months after surgery

#### **Method of measurement**

parallel technic by means of digital sensor size 2(Soredex.Helsinki-finland)by Rinndentsply film holder

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group : open flap debridement with chitosan with high molecular weight (MW800000-600000)

#### **Category**

Treatment - Surgery

#### 2

#### **Description**

Intervention group: open flap debridement with chitosan with low molecular weight (MW300000-100000)

#### **Category**

Treatment - Surgery

#### 3

#### **Description**

Control group: Open flap debridement

#### **Category**

Treatment - Surgery

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Periodontology departmet of Babol dental faculty

##### **Full name of responsible person**

Maryam Faghani

##### **Street address**

Ganjafrooz Ave.

##### **City**

Babol

##### **Province**

Mazandaran

##### **Postal code**

4717647745

##### **Phone**

+98 11 3220 7918

##### **Email**

mary7.pgx87@yahoo.com

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Babol University of Medical Sciences

##### **Full name of responsible person**

Niloofar Jenabian

##### **Street address**

Ganjafrooz Ave.

##### **City**

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##### **Email**

n.jenabian@mubabol.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Babol 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**

Academic

### **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Babol University of Medical Sciences

##### **Full name of responsible person**

Niloofar Jenabian

##### **Position**

Associated professor

##### **Latest degree**

Specialist

##### **Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Nilloofar Jenabian

**Position**

Associated professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Maryam Faghani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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**Email**

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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