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
Niloofar Jenabian

Name of organization / entity
Dental Faculty of University of Babol University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 11 1229 1408

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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 evaluater 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 begining of study and immediately before surgery, 6 and 12 months after sergury
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.
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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
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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 professer
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

Niloofar Jenabian

Position

Associated professer

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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Position

Resident

Latest degree

Medical doctor

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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