Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

Clinical and radiographic investigation of the effect of gel containing chitosan in grade II furcation involvement defects

Protocol summary

Study aim
Clinical and radiographic investigation of the effect of gel containing chitosan in grade II furcation involvement defects

Design
clinical trial has a control group with parallel and double blind groups, each group has 22 sample size, Kitset.ir site randomization process and random number option.

Settings and conduct
The study is double-blind, and the researcher, analyst, and participant do not know the contents of the gels.The intended parameters are measured at the beginning of the study and 6 months after surgery. The flap surgery procedures were performed and the lesions were randomly placed in one of the two treatment groups. Digital subtraction of images before and after treatment is done. Radiolucency is analyzed as analysis and radioopacity as bone formation or lack of Babol University

Participants/Inclusion and exclusion criteria
Inclusion: Patients with moderate to severe chronic periodontitis with grade II furcation involvement on the lingual or buccal side of the first or second molar of the lower jaw. The index plate before surgery is less than 20% and the amount of horizontal penetration of the probe is greater than or equal to 3 Exclusion criteria: systemic problems or drugs interfering with surgery and anatomical problems in the area

Intervention groups
The patients were randomly divided into two groups, case and control, and chitosan-containing or chitosan-free gel was used for them.

Main outcome variables
VPD: from the distance between the gingival margin to the point where the gingival epithelium adheres to the surface of the tooth in millimeters VCAL: the distance from the edge of the gingival margin to the CEJ in mm HPD: horizontal penetration of the probe into the furcation in mmGI: degree of redness, inflammation, bleeding Subtraction Radiography: Absence of deformation or bone loss in parallel periapical radiography and Age and gender

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211221053471N1**
Registration date: **2023-12-23, 1402/10/02**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-23, 1402/10/02**
Update count: **0**

Registration date
2023-12-23, 1402/10/02

Registrant information

Name
Parastoo Madieh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3840 5446

Email address
parastoomadieh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-22, 1402/10/01

Expected recruitment end date
2024-06-21, 1403/04/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical and radiographic investigation of the effect of gel containing chitosan in grade II furcation involvement defects

Public title

Investigating the effect of gel containing chitosan in grade II furcation involvement defects

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with moderate to severe chronic periodontitis with grade II furcation involvement on the lingual or buccal side of the first or second molar of the lower jaw and need treatment. .Index plaque before surgery should be less than 20% The horizontal probe depth (Horizontal Probe Depth, HPD) in the involved areas is greater than or equal to 3.

Exclusion criteria:

Having a systemic disease Need for prophylactic antibiotics to prevent bacterial endocarditis Use of medications that interfere with periodontal healing smoking Presence of contraindications for periodontal surgery Teeth with anatomical complications such as CEP, bifurcation ridge, accessory canal and concavity More tooth mobility than class II Presence of decay and repair in the furcation area Presence of evidence of periapical pathology in the clinical or radiographic appearance of the tooth in question The possibility of the patient's lack of acceptable cooperation after the initial periodontal treatment Having a history of coagulation problems

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization process is done based on the Kitset.ir site and the random numbers option, and in each of the samples, a gel containing chitosan and a gel without chitosan are randomly placed.According to the mentioned site, group A includes numbers 29,7,6,8,25,22,16,43,27,31,2,28,44,33,23,9,10,4,12,35,11,32 and group B including numbers 17,37,38,42,26,20,14,24,21,3,13,36,34,39,40,19,15,30,41,5,18,1 is.

Blinding (investigator's opinion)

Double blinded

Blinding description

Me and the professor of surgery, as a researcher and performing surgeries, will not have any information about the contents of the gels, nor will the data analyst and the participants have any information. What does the gel contain.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Second alley on the left, Har St. 21, Shahabnia intersection,Babol

City

Babol

Province

Mazandaran

Postal code

4718773564

Approval date

2023-09-27, 1402/07/05

Ethics committee reference number

IR.MUBABOL.REC.1402.107

Health conditions studied

1

Description of health condition studied

grade II furcation involvement defects

ICD-10 code

XVIII

ICD-10 code description

Symptoms, signs and abnormal clinical and laboratory findings, not elsewhere classified

Primary outcomes

1

Description

(Vertical probing depth) VPD: means the distance between the margin of the gum to the point where the gum epithelium adheres to the surface of the tooth,

which is measured by the probe. To measure the depth of the pocket, the calibrated periodontal probe is inserted from the facial, lingual, mesial and distal surfaces of the tooth so that the tip of the probe is parallel to the longitudinal axis of the tooth, enters the gingival sulcus and the depth of the pocket is measured. The numbers obtained in the file related to Each patient is registered.

Timepoint

At the beginning of the study (before surgery) and 6 months after surgery

Method of measurement

Clinical parameters are measured using a periodontal probe by the examiner. and the parameters are recorded. The initial radiograph (before surgery) will be taken using Rinn Xcp.Dentsply (Sirona.USA-Newyork) protective film and PSP digital sensor (Soredex.Helsinki-Finland) size 2 and for record keeping The occlusion of the patient is performed using Duralay (Reliance.Illiniois-America) molding material from the bite block area of the film holding the patient's occlusion. The images are processed and then saved using PCT (Soredex.Helsinki-Finland) and DFW2.5 software (Soredex.Helsinki-Finland) and recorded 6 months later using a byte block and PSP digital sensor (Soredex. Helsinki-Finland) size 2 and the same exposure parameters, a second radiograph is performed. Then, digital subtraction of the images before and after the treatment is done by Photoshop CS6 software (Adobe systems.California-America). In the cases where the difference in density is observed as radiolucency as analysis, the cases that were observed as radiopacity as bone formation in the area and in cases where the change that is not observed in terms of density are considered unchanged.

2

Description

(Vertical clinical attachment level) VCAL: First, the CEJ of the desired tooth is determined by a probe, the distance from the edge of the margin to this area is recorded by the probe, the difference of this number is the depth of probing VCAL.

Timepoint

At the beginning of the study (before surgery) and 6 months after surgery

Method of measurement

Clinical parameters are measured using a periodontal probe by the examiner. and the parameters are recorded. The initial radiograph (before surgery) will be taken using Rinn Xcp.Dentsply (Sirona.USA-Newyork) protective film and PSP digital sensor (Soredex.Helsinki-Finland) size 2 and for record keeping The occlusion of the patient is performed using Duralay (Reliance.Illiniois-America) molding material from the bite block area of the film holding the patient's occlusion. The images are processed and then saved using PCT (Soredex.Helsinki-Finland) and DFW2.5 software (Soredex.Helsinki-Finland) and recorded 6 months later using a byte block and PSP digital sensor (Soredex. Helsinki-Finland) size 2 and the same exposure parameters, a second radiograph is performed. Then, digital subtraction of the images before and after the treatment is done by Photoshop CS6 software (Adobe systems.California-America). In the cases where the difference in density is observed as radiolucency as analysis, the cases that were observed as radiopacity as bone formation in the area and in cases where the change that is not observed in terms of density are considered unchanged.

3

Description

(Horizontal probing depth) HPD: is the horizontal entry of the probe into the furcation.

Timepoint

At the beginning of the study (before surgery) and 6 months after surgery

Method of measurement

Clinical parameters are measured using a periodontal probe by the examiner. and the parameters are recorded. The initial radiograph (before surgery) will be taken using Rinn Xcp.Dentsply (Sirona.USA-Newyork) protective film and PSP digital sensor (Soredex.Helsinki-Finland) size 2 and for record keeping The occlusion of the patient is performed using Duralay (Reliance.Illiniois-America) molding material from the bite block area of the film holding the patient's occlusion. The images are processed and then saved using PCT (Soredex.Helsinki-Finland) and DFW2.5 software (Soredex.Helsinki-Finland) and recorded 6 months later using a byte block and PSP digital sensor (Soredex. Helsinki-Finland) size 2 and the same exposure parameters, a second radiograph is performed. Then, digital subtraction of the images before and after the treatment is done by Photoshop CS6 software (Adobe systems.California-America). In the cases where the difference in density is observed as radiolucency as analysis, the cases that were observed as radiopacity as bone formation in the area and in cases where the change that is not observed in terms of density are considered unchanged.

Secondary outcomes

1

Description

Gingival recession: if the gingival margin is below the CEJ, we consider its existence as positive, and if the gingival margin is above the CEJ, this parameter is recorded as absent.

Timepoint

At the beginning of the study (before surgery) and 6 months after surgery

Method of measurement

Clinical parameters are measured using a periodontal probe by the examiner. and the parameters are recorded. The initial radiograph (before surgery) will be taken using Rinn Xcp.Dentsply (Sirona.USA-Newyork) protective film and PSP digital sensor (Soredex.Helsinki-Finland) size 2 and for record keeping The occlusion of the patient is performed using Duralay (Reliance.Illiniois-America) molding material from the bite block area of the film holding the patient's occlusion. The images are processed and then saved using PCT (Soredex.Helsinki-

Finland) and DFW2.5 software (Soredex.Helsinki-Finland) and recorded 6 months later using a byte block and PSP digital sensor (Soredex. Helsinki-Finland) size 2 and the same exposure parameters, a second radiograph is performed. Then, digital subtraction of the images before and after the treatment is done by Photoshop CS6 software (Adobe systems.California-America). In the cases where the difference in density is observed as radiolucency as analysis, the cases that were observed as radiopacity as bone formation in the area and in cases where the change that is not observed in terms of density are considered unchanged.

2

Description
Gingival Index: based on the percentage of tooth surfaces. which has inflammation, determines the severity and existence of gingivitis. and Subtraction Radiography based on the formation or lack of bone formation in the parallel periapical

Timepoint
At the beginning of the study (before surgery) and 6 months after surgery

Method of measurement
Clinical parameters are measured using a periodontal probe by the examiner. and the parameters are recorded. The initial radiograph (before surgery) will be taken using Rinn Xcp.Dentsply (Sirona.USA-Newyork) protective film and PSP digital sensor (Soredex.Helsinki-Finland) size 2 and for record keeping The occlusion of the patient is performed using Duralay (Reliance.Illiniois-America) molding material from the bite block area of the film holding the patient's occlusion. The images are processed and then saved using PCT (Soredex.Helsinki-Finland) and DFW2.5 software (Soredex.Helsinki-Finland) and recorded 6 months later using a byte block and PSP digital sensor (Soredex. Helsinki-Finland) size 2 and the same exposure parameters, a second radiograph is performed. Then, digital subtraction of the images before and after the treatment is done by Photoshop CS6 software (Adobe systems.California-America). In the cases where the difference in density is observed as radiolucency as analysis, the cases that were observed as radiopacity as bone formation in the area and in cases where the change that is not observed in terms of density are considered unchanged.

Intervention groups

1

Description
Intervention group: A gel containing chitosan is randomly placed in each of the samples.

Category
Treatment - Surgery

2

Description
Control group: Chitosan-free gel is randomly placed in each sample.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Babol University of Medical Sciences-Faculty of Dentistry-Department of Periodontology

Full name of responsible person
Parastoo Madieh

Street address
Second alley on the left٫Har St. 21, Shahabnia intersection,Babol

City
Babol

Province
Mazandaran

Postal code
4718773564

Phone
+98 991 151 0075

Email
parastoomadieh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Hassan Alizadeh Afrozi

Street address
Second alley on the left٫Har St. 21, Shahabnia intersection,Babol

City
Babol

Province
Mazandaran

Postal code
4718773564

Phone
+98 991 151 0075

Email
parastoomadieh@gmail.com

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

Parastoo Madieh

Position

resident

Latest degree

Ph.D.

Other areas of specialty/work

Periodontology resident

Street address

Second alley on the left؛Har St. 21, Shahabnia intersection,Babol

City

Babol

Province

Mazandaran

Postal code

4718773564

Phone

+98 991 151 0075

Email

parastoomadieh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Parastoo Madieh

Position

Resident

Latest degree

Ph.D.

Other areas of specialty/work

Dentistry

Street address

Second alley on the left؛Har St. 21, Shahabnia intersection,Babol

City

Babol

Province

Mazandaran

Postal code

4718773564

Phone

+98 51 3840 5446

Fax

Email

parastoomadieh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Parastoo Madieh

Position

Resident

Latest degree

Ph.D.

Other areas of specialty/work

Dentistry

Street address

Second alley on the left؛Har St. 21, Shahabnia intersection,Babol

City

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Province

Mazandaran

Postal code

4718773564

Phone

+98 51 3840 5446

Fax

Email

parastoomadieh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data and outcome changes are available

When the data will become available and for how long

After completing the study

To whom data/document is available

All researchers related to the subject

Under which criteria data/document could be used

According to the relevant protocol

From where data/document is obtainable

Researcher in charge via e-mail

What processes are involved for a request to access data/document

E-mail and then check the reason for the need for data

Comments

Confidentiality of patients' personal information is maintained.