Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of effect of phenytoin mucoadhesive paste 1% after non-surgical therapy on improvement of periodontal status in moderate to severe chronic periodontitis patients

Protocol summary

Summary

Objectives: Main purpose of this study was evaluation the effect of Phenytoin on periodontium. Design: This double blind, split mouth has been conducted on 20 patients with moderate to severe chronic periodontitis. Setting and conduct: After sampling, the average of Periodontal pocket depth along three areas of each tooth (mesial, distal, buccal), Bleeding on probing and modified gingival index (MGI) are recorded. Then for all patients, the first phase of periodontal treatment is accomplished including oral hygiene instructions, scaling and root planning. In each patient, gingival facial surfaces of posterior sextant are randomly selected, one side to apply phenytoin mucoadhesive paste 1% and the other side as a control for placing placebo. Then instructions about the application of the paste are given to all patients. Two Paste containers' lids are selected in different colors and only the side of usage (right or left) was determined on the containers. Patient should apply the pastes twice a day after tooth-brushing and using dental floss for a week. Then patients will be visited 3 weeks after the application of topical phenytoin to evaluating the indices. major eligibility criteria including: No systemic diseases, not taking medications affecting periodontium, no history of antibiotic therapy within the last three months, having at least two similar teeth on each sextants without any decays or restorations and filling informed consent form. The exclusion criteria are included as inappropriate control plaque, irregular use of pastes and not taking part in following up appointments. Intervention: We apply phenytoin mucoadhesive paste on one side of each patient and placebo for the other side. main outcome measures (variables): Periodontal pocket depth, Bleeding on probing and modified gingival index were measured to evaluate the efficiency of drug.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081718834N1**
Registration date: **2015-02-07, 1393/11/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-02-07, 1393/11/18

Registrant information

Name

Nahid Nasrabadi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences of Yazd

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi university of medical sciences of Yazd

Expected recruitment start date

2015-01-30, 1393/11/10

Expected recruitment end date

2015-03-18, 1393/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of effect of phenytoin mucoadhesive paste 1% after non-surgical therapy on improvement of periodontal status in moderate to severe chronic periodontitis patients

Public title
Effect of phenytoin mucoadhesive paste 1% on periodontal parameters

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria were considered as follows: having ability to read and write, no systemic diseases such as diabetes or heart disease, not taking medications affecting periodontium (anti- hypertensives, immune suppressants and anticonvulsants), not being pregnant, no smoking, no traumatic occlusion, no history of antibiotic therapy within the last three months, having at least two similar teeth on each sextants without any decays or restorations and filling informed consent form. In addition we consulted with internist about any drug interactions to phenytoin in patients of our study. The exclusion criteria were considered as follows: 1) inappropriate control plaque during the study. 2) irregular use of pastes on the basis of given instructions 3) not taking part in following up appointments.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Sadoughi University of Medical Sciences of Yazd

Street address
Shahid Bahonar Square, Yazd, Iran

City
Yazd

Postal code

Approval date
2014-05-11, 1393/02/21

Ethics committee reference number
17/1/31880/پ

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
pocket depth

Timepoint
4 weeeks

Method of measurement
milimeters by Williams’s periodontal probe

2

Description
bleeding on probing

Timepoint
4 weeks

Method of measurement
percentage

3

Description
modified gingival index

Timepoint
4 weeks

Method of measurement
grading by observation

Secondary outcomes

empty

Intervention groups

1

Description
In control side after the first phase of periodontal

treatment was accomplished which including oral hygiene instructions, scaling and root planning, instructions about the application of the paste was given to all patients. This placebo paste is contained of 50 grams of mucoadhesive polymers including carbomer 934 and (Hydroxypropyl)methyl cellulose (1:1 w/w). subsequently, the mixed powders were gradually livigated with 50 grams of liquid paraffin.patients should use the paste on the buccal surface of determined side twice a day after tooth-brushing and using dental floss for a week.

Category

Placebo

2

Description

After the first phase of periodontal treatment was accomplished which including oral hygiene instructions, scaling and root planning, instructions about the application of the paste was given to all patients.To prepare Phenytoin paste one gram of phenytoin powder was mixed with 50 grams of mucoadhesive polymers including carbomer 934 and (Hydroxypropyl)methyl cellulose (1:1 w/w). subsequently, the mixed powders were gradually livigated with 50 grams of liquid paraffin.patients should use the paste on the buccal surface of determined side twice a day after tooth-brushing and using dental floss for a week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

periodontology department of dental school of Yazd

Full name of responsible person

Nahid Nasrabadi

Street address

Department of Periodontics, Shahid Sadoughi Dental Faculty, Dahey Fajr BLV, Imam Ave

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shahid Sadoughi Dental Faculty

Full name of responsible person

Dr Hakime Ahadian

Street address

Shahid Sadoughi Dental Faculty, Dahey Fajr BLV, Imam Ave

City

Yazd

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 of Shahid Sadoughi Dental Faculty

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

Dental school of Yazd

Full name of responsible person

Dr Nahid Nasrabadi

Position

Resident of periodontics

Other areas of specialty/work

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Dr Nahid Nasrabadi

Position

Resident of periodontics

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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