

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 weeks

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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Position

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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