

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 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)

##### Phone

+98 35 1621 2623

##### Email address

nasran@mums.ac.ir

##### 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**

millimeters 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****Street address**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Dental school of Yazd

**Full name of responsible person**

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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*