

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

EFFECT OF %1 PHENYTOIN SUSPENSION ON HEALING OF GINGIVAL WOUNDS AFTER FLAP SURGERY

Protocol summary

Summary

Patients with chronic periodontal pocket depth of more than 5 mm requires surgical phase for treatment and one of the biggest consequences of periodontal surgery is ulceration and pain in the site of surgery that is a reason for patients refuse of this type of treatment. Based on these and positive effects of topical phenytoin in accelerating wound and periodontal skin healing and its effect on pain after surgery also, present study aimed to investigate the effect of phenytoin %1 gel on the gums wound healing and reduce pain after periodontal flap surgery. In this prospective, randomized clinical trial that is conducted in Bandar Abbas, Iran in 2015, 60 patients who were systemically healthy; non-pregnant; non-smoker and with periodontal disease symmetrically in two areas selected and Modified widman flap surgery is performed on them. In each patient an area is considered as the control area that before pocket stitching, that area with saline (solution B) are filled and on the other side, the pocket before suturing is filled with phenytoin 1% solution (solution A). On 10 days and 1 and 3 months after surgery, patients are examined. In these visits the patients are questioned about the intensity of pain in two areas (in 3 methods: VAS, option selection and Von Korff).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041533444N1**

Registration date: **2017-05-08, 1396/02/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-08, 1396/02/18

Registrant information

Name

Aida Rashidi

Name of organization / entity

Hormozgan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 917 960 5228

Email address

sarafraz@kish.sharif.edu

Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences

Expected recruitment start date

2017-04-22, 1396/02/02

Expected recruitment end date

2017-10-24, 1396/08/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

EFFECT OF %1 PHENYTOIN SUSPENSION ON HEALING OF GINGIVAL WOUNDS AFTER FLAP SURGERY

Public title

EFFECT OF %1 PHENYTOIN SUSPENSION ON HEALING OF GINGIVAL WOUNDS AFTER FLAP SURGERY

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: systemic health; non pregnant; non smoking; need surgery in both sides and no need for bone reconstruction.

Age

From **20 years** old to **63 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Hormozgan University of Medical Sciences

Street address

Hormozgan University of Medical Sciences, Chamran blvd.

City

Bandar Abbas

Postal code

Approval date

2017-04-08, 1396/01/19

Ethics committee reference number

IR.HUMS.REC.1395.140

Health conditions studied

1

Description of health condition studied

Periodontal diseases

ICD-10 code

K05.6

ICD-10 code description

Periodontal disease, unspecified

Primary outcomes

1

Description

Cohesion of connective tissue

Timepoint

Before, 10 days & 3 month after surgery

Method of measurement

Clinical examination

2

Description

Pain

Timepoint

Before, 10 days & 3 month after surgery

Method of measurement

Questionnaire / Clinical observation

Secondary outcomes

1

Description

Gingival enlargement

Timepoint

Before, 10 days & 3 month after surgery

Method of measurement

Clinical examination

Intervention groups

1

Description

after selected one part as test part, will use phenytoin suspension in that part before suture

Category

Treatment - Drugs

2

Description

in other side, will use normal saline before suture

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dentistry clinic

Full name of responsible person

Rouhollah Etemadifar

Street address

Dr. Etemadifar Clinic, Fatemiyeh St.

City

Bandar Abbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hormozgan University of Medical Sciences
Full name of responsible person
 Rouhollah Etemadifar
Street address
 Faculty of Dentistry, Chamran blvd.
City
 Bandar Abbas
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Hormozgan University of Medical Sciences
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
 Hormozgan University of Medical Sciences
Full name of responsible person
 Aida Rashidi
Position
 Student of Dentistry
Other areas of specialty/work
Street address
 Faculty of Dentistry, Chamran blvd.
City
 Bandar Abbas
Postal code
Phone
 +98 76 3367 6611
Fax
Email
 aida_rashidi_1370@yahoo.com;
 aidarashidi684@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
 Hormozgan University of Medical Sciences

Full name of responsible person
 Rouhollah Etemadifar
Position
 Faculty member
Other areas of specialty/work
Street address
 Faculty of Dentistry, Chamran blvd.
City
 Bandar Abbas
Postal code
Phone
 +98 76 3333 5045
Fax
Email
 Aidarashidi684@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
 Hormozgan Faculty of Dentistry
Full name of responsible person
 Aida Rashidi
Position
 Medical student
Other areas of specialty/work
Street address
 Hormozgan University of Medical Sciences, Golshahr st.
City
 Bandar Abbas
Postal code
Phone
Fax
Email
 Aidarashidi684@gmail.com
Web page address

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