Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jun 2026

The effect of anaheal tablet after flap removal pocket surgery

Protocol summary

Study aim
Determining the effect of anaheal tablets after flap removal envelopes in medical centers of Bandar Abbas

Design
The study is a clinical trial and will be conducted in two blinds. The study population included people with chronic periodontitis who need envelope removal surgery after completing phase I periodontitis. The randomly selected individuals will be divided into two equal groups. All demographic information will be recorded before any intervention. Periodontal indices in both groups will be measured accurately. gingival index, plaque index and bleeding on probing indices will be measured according to the standard methods of articles. Envelope removal flap surgery will be performed by a periodontist according to the usual and standard methods, depending on the type of envelope and case. The first group will be given 500 mg of Anahil capsules twice a day, one hour before a meal after surgery, and the second group will be given a placebo tablet or capsule. Four weeks and eight weeks after surgery, periodontal indices will be measured again in both groups

Settings and conduct
A double-blind trial study in patients in need of envelope removal surgery referred to special offices of periodontists in Bandar Abbas

Participants/Inclusion and exclusion criteria
Inclusion criteria: People aged 18-70 years with chronic periodontitis who need envelope removal surgery after completing phase I periodontal Exclusion criteria: Having a systemic disease Smoking

Intervention groups
The intervention group is given 500 mg of Anahil capsules twice a day, one hour before a meal, after surgery. The placebo group of placebo tablets or capsules is given twice a day, one hour before a meal.

Main outcome variables
gingival index, plaque index and bleeding on probing

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20201106049289N1**
Registration date: **2021-04-06, 1400/01/17**
Registration timing: **prospective**

Last update: **2021-04-06, 1400/01/17**
Update count: **0**

Registration date
2021-04-06, 1400/01/17

Registrant information
Name
Arad Mirzaagha
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 4401 3227
Email address
aradf44@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-18, 1400/01/29
Expected recruitment end date
2021-04-18, 1400/01/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of anaheal tablet after flap removal pocket

surgery

Public title
The effect of anaheal tablet after flap removal pocket surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People with chronic periodontitis who need envelope removal surgery after completing phase I periodontitis
Exclusion criteria:
Having a systemic disease Smoking
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **26**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done simply by tossing coins and participants will be divided into two intervention groups and a control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient receives the drug (intervention or comparison group) in sealed packets that are coded. The coding is done by one of the project partners and the dentist and the patient are blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Hormozgan University of Medical Sciences
Street address
Shahid Chamran Street
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Approval date
2021-03-03, 1399/12/13
Ethics committee reference number
IR.HUMS.REC.1399.562

Health conditions studied

1

Description of health condition studied
Periodontal disease
ICD-10 code
K05.6
ICD-10 code description
Periodontal disease, unspecified

Primary outcomes

1

Description
BOP values
Timepoint
Before therapeutic intervention and one month after the intervention
Method of measurement
BOP: Each tooth is probed on four levels: mesial, distal, buccal and lingual. Insert the probe gently and gently to the depth of the envelope and remove it. positive and otherwise considered BOP negative

2

Description
GI score PI index plate score
Timepoint
Measurement is performed at baseline, one week after surgery and 4 weeks after surgery
Method of measurement
Using the percentage of painted surfaces of teeth after using detectors

3

Description
Depth of Probe
Timepoint
Before therapeutic intervention and one month after the intervention
Method of measurement
Using the percentage of painted surfaces of teeth after using detectors

Secondary outcomes

1

Description
removal pocket
Timepoint

Periodontal indices will be re-measured in both groups before, four weeks and eight weeks after surgery.

Method of measurement

GI , PI and BOP indices will be measured according to the standard methods of articles.

Intervention groups

1

Description

Intervention group: Intervention group: Before surgery, Gingival Index, plaque index and Bleeding on Probing indices will be measured according to standard methods. Then, 500 mg of Anahil capsules is given twice a day, one hour before a meal, after surgery. In the first week and week 4 after surgery, GI, PI and BOP re-indices will be measured according to standard methods.

Category

Treatment - Drugs

2

Description

Control group: Before surgery, Gingival Index, plaque index and Bleeding on Probing indices will be measured according to standard methods. Then the second pill or capsule is given twice a day after surgery, one hour before a meal. In the first week and week 4 after surgery, GI, PI and BOP re-indices will be measured according to standard methods.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Private offices of periodontal specialists

Full name of responsible person

Dr. Hossein Babazadeh

Street address

Shahid Chamran Street

City

Bandar Abbas

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Hormozgan

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7916613885

Phone

+98 76 3333 3280

Email

Babazadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandarabbas university of medical sciences

Full name of responsible person

Dr. Teimour Aghamolaei

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Shahid Chamran Street

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bandarabbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr. Hossein Babazadeh

Position

Professor of Periodontology

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Bandare-abbas University of Medical Sciences

Full name of responsible person
Dr. Hossein Babazadeh

Position
Professor of Periodontology

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
..

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available