

# 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

##### **Province**

Hormozgan

##### **Postal code**

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

##### **Street address**

Shahid Chamran Street

##### **City**

Bandar Abbas

##### **Province**

Hormozgan

##### **Postal code**

7916613885

##### **Phone**

+98 76 3333 3280

##### **Email**

Babazadeh@yahoo.com

##### **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**

Shahid Chamran Street

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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

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Dr. Hossein Babazadeh

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Postal code**

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**Email**

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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**

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**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