

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparative effect of the mouthwash containing propolis-aloe vera plant extract and chlorhexidine solution on plaque and gingival bleeding indexes in Generalized marginal gingivitis patients.

#### Protocol summary

##### Study aim

Comparison of the effect of mouthwash containing propolis- Aloe vera herbal extract and Chlorhexidine solution on plaque index and gingival bleeding in people with generalized marginal gingivitis.

##### Design

A single blind clinical trial with two intervention groups and one control group on 60 patients.

##### Settings and conduct

60 people who refer to the Research Center of Tabriz University of Medical Sciences are randomly assigned to one of 3 groups in a single-blind manner. After primary recording indexes they receive a coded bottle of mouthwash from the nurse . The patients are told to use the mouthwashes twice a day for two weeks. After the end of the second week, the patients are called and the gingival, plaque and bleeding index during probing are recorded and the information is subjected to statistical analysis.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Suffering from generalized marginal gingivitis, have not received antibiotics in the past 6 months . Not committed systemic diseases that causes generalized gingivitis. Not suffering periodontitis. Exclusion criteria : Patients with cardiovascular diseases and diabetes. Patients who smoke, have chronic or acute infections.

##### Intervention groups

Intervention group 1: using BEHSA 0.2% chlorhexidine mouthwash for 14 days, 10 ml twice a day After brushing teeth and not eating or drinking for half an hour. intervention group 2: use of aloe vera propolis mouthwash Water based 50 percent (formulated in Tabriz Faculty of Pharmacy)10 ml twice a day for 14 days After brushing teeth and not eating or drinking for half an hour. control group: using NIKOO SHIMI distilled water as a mouthwash for 14 days twice a day 10 ml After

brushing teeth and not eating or drinking for half an hour

##### Main outcome variables

Plaque index in probing, bleeding in probing, Depth of envelope in probing

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220717055482N1**

Registration date: **2023-06-18, 1402/03/28**

Registration timing: **retrospective**

Last update: **2023-06-18, 1402/03/28**

Update count: **0**

##### Registration date

2023-06-18, 1402/03/28

##### Registrant information

##### Name

Sayna Jahed

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3328 0495

##### Email address

saynaja@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-11, 1401/09/20

##### Expected recruitment end date

2023-02-09, 1401/11/20

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparative effect of the mouthwash containing propolis-aloë vera plant extract and chlorhexidine solution on plaque and gingival bleeding indexes in Generalized marginal gingivitis patients.

**Public title**  
effect of the mouthwash containing propolis-aloë vera plant

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
patients with Generalized marginal gingivitis Have not received antibiotics in the last 6 months. Not in puberty or pregnant Do not have systemic diseases that cause generalized gingivitis. patients which not committed to periodontitis

**Exclusion criteria:**  
Patients with cardiovascular diseases and diabetes  
People who smoke. Patients with chronic or acute infections. uncontrolled diabetics

**Age**  
No age limit

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: 60

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, the permutation block method will be used to randomly assign patients to the studied treatment groups. For this purpose, 20 blocks of three will be created including the studied treatments, in each block a random sequence of A, B, C will be created. The blocks will be randomly selected and based on the sequence in each group of patients, they will be assigned to 3 treatment groups from the beginning of the list of patients. To create a random sequence, a table of random numbers will be used.

**Blinding (investigator's opinion)**  
Not 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 Tabriz university of medical sciences

##### Street address

Research and Technology Vice-Chancellor 3rd Floor ,Central Building No 2 ,Tabriz University of Medical Sciences , Golgasht Street ,Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5157686977

#### Approval date

2022-06-27, 1401/04/06

#### Ethics committee reference number

IR.TBZMED.REC.1401.303

## Health conditions studied

### 1

#### Description of health condition studied

gingivitis

#### ICD-10 code

K05.1

#### ICD-10 code description

Chronic gingivitis

## Primary outcomes

### 1

#### Description

Plaque index in probing

#### Timepoint

before intervention and 2 weeks after intervention

#### Method of measurement

inclusive tablet ,Williams probe

### 2

#### Description

bleeding in probing

#### Timepoint

before intervention and 2 weeks after intervention

#### Method of measurement

inclusive tablet ,Williams probe

### 3

#### Description

Depth of envelope in probing

**Timepoint**

before intervention and 2 weeks after intervention

**Method of measurement**

inclusive tablet ,Williams probe

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Control group: They receive distilled water, . Patients are asked to rinse their mouth twice a day with the mouthwash they have for 14 days.

**Category**

Placebo

**2****Description**

Intervention group 1 :BEHSA Chlorhexidine 0.2%. Patients are asked to rinse their mouth twice a day each turn 10 ml with the mouthwash they have for 14 days.

**Category**

Treatment - Drugs

**3****Description**

Intervention group 2: Aloe vera propolis 50% water base (formulated in Tabriz Faculty of Pharmacy) , patients are taught to use 10 cc of the related mouthwash twice a day for two weeks after brushing their teeth, and after 1 minute, they should pour the mouthwash out of their mouth and avoid eating and drinking for half an hour, the patients are then called after the end of the second week and the gingival index, plaque index and bleeding during probing are recorded.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Faculty of Dentistry, Periodontal Department, Research Center of Tabriz University of Medical Science

**Full name of responsible person**

masoume faramarzi

**Street address**

first floor entrance 3, Faculty of Dentistry, Golgasht St, Tabriz, East Azerbaijan

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tabriz

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5166614711

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info@dentistryfac.tbzmed.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Parviz Shahaby

**Street address**

3rd floor of Research and Technology Vice-Chancellor, Tabriz University of Medical Sciences, Central Building No. 2, Golgasht Street, Tabriz

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research-vice@tbzmed.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Tabriz university of medical science

**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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Sayna Jahed

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

Student

**Latest degree**

A Level or less

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Student

**Latest degree**

A Level or less

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available