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-aloe 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-aloe 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: Aloevera 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 faramarzy
Street address
first floor entrance 3,Faculty of Dentistry,Golgasht St,Tabriz,East Azerbaijan
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Postal code
5166614711
Phone
+98 41 3335 5965
Email
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
City
Tabriz
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East Azarbaijan
Postal code
5166614711
Phone
+98 41 3334 4280
Email
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
Street address

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Position
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Person responsible for updating data

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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