

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of Aloe Vera and Paradontax herbal toothpastes on plaque, bleeding and mild to moderate gingivitis: a clinical trial study

Protocol summary

Study aim

Comparison of Aloe Vera and Paradontax herbal toothpaste efficacy on the plaque, bleeding and mild to moderate gingivitis in Guilan dental school students in the academic year 99-1400

Design

Randomized, parallel, and double-blind clinical trial. To determine the sample size concerning the repetition of the measurements in 2 groups for each individual, the effect of each individual must be regarded. So the suitable formula with duplicate sizes is used. Considering 4 repetition, a correlation of 0.50, the statistical power of 80%, error level of 0.05, and standard deviation of previous studies based on plaque index equal to 0.55, the minimum sample size equal to 20 for each group. It has been found that considering the probability of specimen shedding in each group, 24 individuals are considered. The trial is in phase 3.

Settings and conduct

Students of Guilan Dental School will be selected by the available sampling method after the initial examination according to the inclusion criteria. They are randomly divided into two groups, and the examiner who measures and records the indicators is generally unaware of the study process.

Participants/Inclusion and exclusion criteria

Patients are selected from non-smoker youth with mild gingivitis, at least 20 teeth and a complete health situation, free of periodontal pockets, clinical attachment loss, systemic problems, use of medications affecting the periodontium. Also, they must not have been received non-surgical and surgical periodontal treatments during the one and three past months.

Intervention groups

Patients are divided into two groups of Aloe Vera and Paradontax toothpaste recipients. Both are given standard health instruction and determined toothpaste at the beginning of the study.

Main outcome variables

Primary outcomes include: Dental plaque index, gingival bleeding index, gingivitis index.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080824001081N10**

Registration date: **2020-05-28, 1399/03/08**

Registration timing: **prospective**

Last update: **2020-05-28, 1399/03/08**

Update count: **0**

Registration date

2020-05-28, 1399/03/08

Registrant information

Name

Golpar Radafshar

Name of organization / entity

Guilan University of Medical Sciences, School of dentistry

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-20, 1399/03/31

Expected recruitment end date

2020-12-09, 1399/09/19

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Aloe Vera and Paradontax herbal toothpastes on plaque, bleeding and mild to moderate gingivitis: a clinical trial study

Public title
Comparison of the effect of two herbal toothpastes on dental plaque control and mild to moderate gingivitis

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18 to 22 years Agreement upon signing an informed consent Patients with mild chronic gingivitis with MGI score = 1 having at least 20 standing teeth
Exclusion criteria:
Patients with any systemic disease according to patient's history The presence of dental prostheses in the form of bridges The presence of orthodontic appliances The presence of severe crowding Mouth breathing with inadequate upper lip coverage by clinical examination The presence of any periodontal pockets (depth > 3 mm with) Clinical attachmet loss more than 1mm Smoking Use of any antibiotics and medications that have gum issues such as gingival enlargement over the past month. Receive any non-surgical or surgical periodontal treatment during the past three months

Age
From **18 years** old to **22 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple block randomization method using excel software. Individuals as units of randomization. The sequence builds as follows: Block identifier, block size, sequence within block, treatment group, intervention code.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this research, the clinical examiner who evaluates and records the periodontal indices at baseline, 1 and 3 months post intervention is blinded to the case and control groups. Toothpaste tubes are also identified by white coatings to blind the study participants

Placebo

Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Dental Faculty of Guilan University of Medical Sciences, Fuman-Saravan Highway

City

Rasht

Province

Guilan

Postal code

41941-73774

Approval date

2020-05-06, 1399/02/17

Ethics committee reference number

IR.GUMS.REC.1399.036

Health conditions studied

1

Description of health condition studied

Chronic plaque-induced gingival inflammation

ICD-10 code

K05.10

ICD-10 code description

Chronic gingivitis, plaque induced

Primary outcomes

1

Description

plaque index

Timepoint

Baseline, one, two and three months post-intervention

Method of measurement

Tureskey-Gilmore -Gllilckman modification of the Quigley-Hein Plaque index and Rustogi Modification of the modified Navy Plaque index

2

Description

Gingival inflammation

Timepoint

Baseline, one, two and three months post-intervention

Method of measurement

Modified gingival index

3

Description

Gingival bleeding

Timepoint

Baseline, one, two and three months post-intervention

Method of measurement

Gingival bleeding index, Ainamo & Bay

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First intervention group, Aloe Vera toothpaste recipient: All patients receive Modified Bass toothbrush training and are advised to use as much pea toothpaste as possible. Brush twice daily for 5 minutes each day.

Category

Prevention

2

Description

Intervention group: Second intervention group, Parodontax toothpaste recipient: Similar to the first group, all patients are trained in the method of brushing using the Modified Bass method, and they are advised to use the same amount of toothpaste as the pea seed in each serving. Brush twice daily for 5 minutes each day.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontics, Faculty of Dentistry,
Guilan University of Medical Sciences

Full name of responsible person

Athena Khaleghian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Naghipoor

Street address

6th floor, central building of the Gilan University of
Medical Sciences, opposite Azodi stadium, Namjoo
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Grant name

Grant code / Reference number

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

No

Title of funding source

Researchers

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr, Golpar Radafshar

Position

Associate professor of Periodontology, Department of
Periodontics

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Dr, Golpar Radafshar

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Athena Khaleghian

Position

Dental student

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

Participants do not consent that their data get published.

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

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

Title and more details about the data/document

Since we intend to publish an article based on the present research, the only available data is through the potential article.

When the data will become available and for how long

Within the next 6-8 months the article will get ready for submission and an exact date of publication is not predictable since it depends on the assigned journal policy.

To whom data/document is available

Researchers intend to publish the article in an open access journal so all the stakeholders and interested professionals will be able to access to the content.

Under which criteria data/document could be used

This research will be published in line with the international and national goal for improving dental and periodontal hygiene instruction among young adults.

From where data/document is obtainable

Searching the article key words in any search engine would guide the interested people to the article.

What processes are involved for a request to access data/document

No particular process will not be necessary.
Comments