

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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)

##### Phone

+98 13 1323 0775

##### Email address

golshad@gums.ac.ir

##### 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

##### **Street address**

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

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+98 13 3322 9599

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+98 13 3332 2444

##### **Email**

research@gums.ac.ir

##### **Web page address**

http://www.gums.ac.ir/research

## **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  
Street

##### **City**

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##### **Province**

Guilan

##### **Postal code**

41446-56513

##### **Phone**

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##### **Fax**

##### **Email**

research@gums.ac.ir

##### **Web page address**

##### **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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**Latest degree**

Medical doctor

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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**

Associate professor of Periodontology, Department of Periodontics

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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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**