

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparing the effect of Dental Flosses containing Fluoride, Benzylamine and Aloe vera on Periodontal Indexes in Gingivitis

Protocol summary

Study aim

Comparing the effect of Dental Flosses containing Fluoride, Benzylamine and Aloe vera on Periodontal Indexes in Gingivitis

Design

In this clinical trial study, the sample size will be determined using the previous articles, considering the 95% confidence level, 15 individuals in each group. Patients with gingivitis and those with inclusion criteria who referred to the Dental Clinic of Rasht will be selected. Participants will randomly divided into three intervention groups: one, two, and three based on a random number table.

Settings and conduct

This study will be conducted in Dental Clinic of Rasht. Patients will be entered into the study after obtaining informed consent regarding the inclusion and exclusion criteria and will be randomly divided into three groups. In the first intervention group, Marjan's No Wax Dental floss, containing fluoride, in the second group, Marjan's No Wax Dental floss, containing aloe vera and in the third group Marjan's No Wax Dental floss, containing benzidamine will be used for each patient once a day for one week. The modified gingival index will be evaluated at the beginning of the study, on days 7 and 14, by examination and observation.

Participants/Inclusion and exclusion criteria

major inclusion and exclusion criteria: Patients Aged over 20-50 years, with gingivitis and No history of smoking were included; Patients who have orthodontic treatment, Patients with hypertension or diabetes or taking immunomodulatory drugs were excluded

Intervention groups

In the first intervention group, Marjan's No Wax Dental floss, containing fluoride, in the second group, Marjan's No Wax Dental floss, containing aloe vera and in the third group Marjan's No Wax Dental floss, containing benzidamine will be used for each patient once a day for one week.

Main outcome variables

Modified Gingival Index (MGI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191026045248N1**

Registration date: **2019-11-25, 1398/09/04**

Registration timing: **retrospective**

Last update: **2020-01-05, 1398/10/15**

Update count: **1**

Registration date

2019-11-25, 1398/09/04

Registrant information

Name

Naser Jurebrahimiyan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3348 6418

Email address

jurnaser@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-19, 1398/01/30

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

2019-04-19, 1398/01/30

Actual recruitment end date

2019-07-21, 1398/04/30

Trial completion date

2019-07-21, 1398/04/30

Scientific title

Comparing the effect of Dental Flosses containing Fluoride, Benzylamine and Aloe vera on Periodontal Indexes in Gingivitis

Public title

Comparing the effect of Dental Flosses containing Fluoride, Benzylamine and Aloe vera on Periodontal Indexes in Gingivitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

20-50 years old gingivitis No smoking

Exclusion criteria:

Patients with orthodontic treatment Patients with hypertension or diabetes Patients taking immunomodulatory drugs

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **45**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be used by the blocking method. For this purpose, letter A represents the first intervention group and letter B represents the second intervention group and letter C represents the third intervention group and two patterns will be assumed ABC and CBA; If in Random number table, the even numbers come out ABC will be used and if the odd one comes CBA will be used.

Blinding (investigator's opinion)

Not blinded

Blinding description**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

Vice Chancellor for Research and Technology,
Opposite 17 Shahrivar Hospital, Shahid Siadati Ave.,
Namjoo Street Ave.

City

Rasht

Province

Guilan

Postal code

4188794755

Approval date

2019-04-13, 1398/01/24

Ethics committee reference number

IR.GUMS.REC.1398.010

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**

Modified Gingival Index (MGI)

Timepoint

At the beginning of study, seventh day and fourteenth day

Method of measurement

Observation and Evaluation

Secondary outcomes

empty

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

Intervention group 1 : Marjan's No Wax Dental floss, containing fluoride for each patient once a day for one week.

Category

Treatment - Devices

2**Description**

Intervention group 2 : Marjan's No Wax Dental floss, containing aloe vera for each patient once a day for one week.

Category

Treatment - Devices

3

Description

Intervention group 2 : Marjan's No Wax Dental floss, containing Benzydamine for each patient once a day for one week.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasht Dental Clinic

Full name of responsible person

Hani Naderi

Street address

Guilan Dental Clinic, Opposite of Pardis Hotel, Imam Khomeini Ave.

City

Rasht

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Guilan

Postal code

4188794755

Phone

+98 13 3348 6406

Email

Haninaderi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Reza Naghipor

Street address

Vice Chancellor for Research and Technology,
Opposite 17 Shahrivar Hospital, Shahid Siadati Ave.,
Namjoo Street Ave.

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Phone

+98 13 3333 5821

Email

research@gums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Naser Jurebrahimian

Position

Dentistry 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

Rasht University of Medical Sciences

Full name of responsible person

Arash ghafoori

Position

Assistant Professor

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

Naser Jurebrahimian

Position

Dentistry student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Province

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Postal code

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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