

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative evaluation of the effectiveness of a Persica-containing toothpaste over a Persica-free toothpaste in patients with plaque-induced gingivitis

Protocol summary

Study aim

Comparison of effectiveness of a Persica-containing toothpaste and a Persica-free toothpaste in plaque induced gingivitis

Design

A clinical trial with the control group, parallel-group, triple-blind, Randomized on 140 patients trial

Settings and conduct

This study takes part in the field of periodontology in the dentistry department of the dental University of medical sciences. Patients with plaque-induced gingivitis will be treated by phase 1 treatment and then will use toothpaste and will be followed up within different intervals. In this study the patient, examiner, analytical counselor, person handling the toothpaste, and the person controlling the study are blind.

Participants/Inclusion and exclusion criteria

The patient must be aged between 18-75. The patient must have More than 20 healthy teeth in their mouth. The patient shouldn't be taking antibiotics or anti-inflammatory drugs continuously. The patient shouldn't be a smoker. The patient shouldn't be pregnant, Lactating mother, and with systemic or immunity disorders and diseases. The patient shouldn't have a restoration, crown, or an unacceptable bridge.

Intervention groups

Intervention group: the group using the Persica-containing toothpaste. Control group: the group using the Persica-free toothpaste.

Main outcome variables

MGI (modified gingival index); FMPS (Full mouth plaque score); FMBS (Full mouth bleeding score)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080831001150N6**

Registration date: **2022-10-16, 1401/07/24**

Registration timing: **prospective**

Last update: **2022-10-16, 1401/07/24**

Update count: **0**

Registration date

2022-10-16, 1401/07/24

Registrant information

Name

Neda Moslemi

Name of organization / entity

Tehran university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 3902

Email address

nmoslemi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of the effectiveness of a Persica-

containing toothpaste over a Persica-free toothpaste in patients with plaque-induced gingivitis

Public title
Effect of a Persica-containing toothpaste in plaque induced gingivitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Ages 18 to 75 The patient must have at least 20 teeth without crown restorations or cavities Patient of plaque induces gingivitis BIP positive or a change in gingival margin color The patient is willing to participate
Exclusion criteria:
The cause of gingivitis isn't plaque Patient has been taking antibiotics or anti inflammatory drugs repeatedly within the past 3 months Pregnant or lactating women Patient with systemic or immunity problems Smoker Pocket depth > 4mm Patient with clinical attachment loss Patient with not acceptable partial prosthesis, restorations or bridges Patient using orthodontic appliances Patient with a history of allergic reactions to chemicals Patient using mouth rinse

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
0

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **130**

Randomization (investigator's opinion)
Randomized

Randomization description
Balanced block randmization: we put people randomly in blocks containing 4 or 6 people. Then half of every block will randomly be in the control and the other half in the intervention Unit of randomization: personal Not using layers of randomization Done by using statical softwares Allocation: files containing the information will be kept with a person who will not be participating or conducting the study

Blinding (investigator's opinion)
Triple blinded

Blinding description
In this study the examiner, analytical counselor, person handing out the toothpastes, patient and the person controlling the study will be blind about which toothpaste is the patient using

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Vice chancellor for research, Tehran University of Medical Sciences

Street address

Ghods st, Keshavarz blvrd

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-06-28, 1401/04/07

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.258

Health conditions studied

1

Description of health condition studied

Plaque induced gingivitis

ICD-10 code

K05.00

ICD-10 code description

Acute gingivitis, plaque induced

Primary outcomes

1

Description

Modified gingival index

Timepoint

Baseline; 1 week; 2 weeks; 1 month; 2 months after phase 1 treatment

Method of measurement

Clinical examination

2

Description

Full mouth plaque score

Timepoint

Baseline; 1 week; 2 weeks; 1 month; 2 months after phase 1 treatment

Method of measurement

Clinical examination

3

Description

Full mouth bleeding score

Timepoint

Baseline; 1 week; 2 weeks; 1 month; 2 months after phase 1 treatment

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: On the first appointment after the clinical periodontal examinations, the patient will receive phase one treatment: Root planing and scaling (SRP), and then will be given a Persica-containing toothpaste (Commercially known as Dentamax herbal toothpaste, Goltash company, Isfahan, Iran) to use twice a day, before sleep and after breakfast, each time in the size of a pea and then brush their teeth using the Rolling method. The patient will also be given dental floss to use after brushing their teeth. later on, the patient will be followed up within a week, two weeks, one month, and two months after the first appointment to record the periodontal indexes. The components of the toothpaste are: Water, Sorbitol, Glycerine, Silica-Ab, Silica-Th, Salvadora Persica extract, S.L.S, C.M.C, NaF, Food Flavoring, C.I.77891, C.I.19140, Caustic soda, Sodium saccharin, Methyl Paraben, Carbomer, C.I.42090

Category

Treatment - Drugs

2

Description

Control group: On the first appointment after the clinical periodontal examinations, the patient will receive phase one treatment: Root planing and scaling (SRP), and then will be given an ordinary toothpaste with similar components as the interventions groups toothpaste but without Persica extract (Goltash company, Isfahan, Iran) to use twice a day, before sleep and after breakfast, each time in the size of a pea and then brush their teeth using the Rolling method. The patient will also be given dental floss to use after brushing their teeth. later on, the patient will be followed up within a week, two weeks, one month, and two months after the first appointment to record the periodontal indexes. The components of the toothpaste are: Water, Sorbitol, Glycerine, Silica-Ab, Silica-Th, S.L.S, C.M.C, NaF, Food Flavoring, C.I.77891, C.I.19140, Caustic soda, Sodium saccharin, Methyl Paraben, Carbomer, C.I.42090

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of dentistry of Tehran university of medical sciences

Full name of responsible person

Neda Moslemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Goltash company, Paksan

Full name of responsible person

Bahram Khosravi

Street address

7th st, Mobarake, Isfahan

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Isfahan

Postal code

8173644673

Phone

+98 31 5237 3350

Email

info@goltash.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Goltash company, Paksan

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

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Houriye Radanfar

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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1439955991

Phone

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

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available