

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

A study to assess the plaque inhibitory action of a herbal-based toothpaste: A double-blind controlled clinical trial

Protocol summary

Summary

The objective of this study is to assess the plaque inhibitory action of a herbal-based toothpaste. 30 adult volunteers were recruited from students of Guilan University meeting the inclusion criteria and having at least 20 teeth with the maximum probing depth equal to 3 millimeters participate in this double-blind, cross-over, controlled clinical trial, based on a variation of a 4-day plaque regrowth model with a 3-day wash-out period. After professional tooth cleaning, subjects are asked to refrain from all mechanical hygiene measures for the next 96 hours and to use two rinses (1min) a day of either test (Paradontax) or control toothpastes as the only oral hygiene measure. At day 4, teeth are stained to assess the whole mouth plaque index (PI) using Tureskey modification of Quigly Hein PI, and to evaluate PI for anterior teeth, using a 10 scaled PI: New Method of Plaque Scoring (Dababneh et al). For the purpose of accuracy photographs are taken from anterior teeth.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138808191081N3**

Registration date: **2010-02-19, 1388/11/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-02-19, 1388/11/30

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

Guilan University of Medical Sciences, Research secretary

Expected recruitment start date

2009-08-04, 1388/05/13

Expected recruitment end date

2009-11-02, 1388/08/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study to assess the plaque inhibitory action of a herbal-based toothpaste: A double-blind controlled clinical trial

Public title

The inhibitory action of a herbal- based toothpaste on dental plaque.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: having systemic health and periodontal health: Pocket probing depth no more than 3 mm, no bleeding on probing and/or gingival enlargement, having at least 20 scorable teeth Exclusion criteria: having dental implants, orthodontic appliances or partial dentures, Drug consumption Particularly Antibiotics, smoking, dental crowding and/or mouth breathing habit.

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features

In this study toothpastes are used as slurries which are made freshly by adding 3 mg toothpaste to 10 ml distilled water

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice-chancellor for Research, Guilan University of Medical Sciences

Street address

Namjoo Blvd., GUMS Building

City

Rasht

Postal code**Approval date**

2010-03-02, 1388/12/11

Ethics committee reference number

8507

Health conditions studied**1****Description of health condition studied**

Dental-microbial plaque

ICD-10 code

K05.1

ICD-10 code description

chronic gingivitis

2**Description of health condition studied**

Dental-microbial plaque

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes**1****Description**

plaque index for the entire dentition

Timepoint

4-day period

Method of measurement

Treskey modification of Quigly-Hein plaque index

Secondary outcomes**1****Description**

Plaque index for anterior teeth

Timepoint

4-day period

Method of measurement

New method of plaque scoring

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

Parodontax(herbal-based) toothpaste slurry, two rinses (1min) a day

Category

Treatment - Other

2**Description**

A commercial toothpaste slurry (with no herbal ingredients), two rinses (1min) a day

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dental research center and department of periodontics, faculty of dentistry

Full name of responsible person

Golpar Radafshar

Street address

Emam Khomeini Blv.opp.Pardis Hotel

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research, Faculty of Dentistry,
Guilan University of Medical Sciences

Full name of responsible person

Nastaran Mirfarhadi

Street address

Opposite Pardis hotel, Emam Khomeini Blv.

City

Rasht

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice-chancellor for Research, Faculty of Dentistry, Guilan
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Dental Research center, Faculty of Dentistry, Guilan
University Of Medical sciences

Full name of responsible person

Nastaran Mirfarhadi

Position

MS Nursing Education/center secretary

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

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Position

Assistant professor in the department of
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report

empty
Analytic Code
empty
Data Dictionary
empty