Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 photographies 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 secretory

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
KO5.1
ICD-10 code description
chronic gingivitis

2

Description of health condition studied
Dental-microbial plaque
ICD-10 code
KO5.3
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 commerical 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

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of periodontics, Dental Research center,faculty of Dentistry,Guilan University of medical

Full name of responsible person

Golpar Radafshar

Position

Assistant professor in the department of periodontology/Head (Director) of dental research center

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Department of periodontics, Dental Research center, Faculty of Dentistry, Guilan University of Medic

Full name of responsible person

Golpar Radafshar

Position

Assistant professor in the department of periodentology/Head of dental research center

Other areas of specialty/work

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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