

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of Green Tea Mouthwash Containing 1 % Tannin on Plaque, Gingivitis and tooth staining

Protocol summary

Summary

This is a randomized, double-blind, controlled, clinical trial which aims to evaluate the effects of green tea mouthwash containing one percent tannin on plaque accumulation, gingivitis, and tooth staining. One tenth percent chlorhexidine mouthwash is used as positive control. 40 subjects recruiting from the students of dentistry faculty of Guilan University of Medical Sciences, all of which are systemically healthy, are not under any medication, do not have dental prostheses, and do not wear orthodontic appliances, participate in this study. Upon entry, they sign an informed consent and randomly assign in case and control groups. Plaque and gingival indices as well as gingival bleeding index are recorded at baseline. Scaling and polishing are performed and plaque index score is decreased to zero. During the study period, participants follow their routine oral hygiene methods and are advised not to use any mouthwash other than their respected one. All the participants are provided with a calibrated cup and mouthwashes in dark, coded bottles and are instructed to use 15 ml of the mouthwash twice daily for 1 minute during the 4 weeks of trial. All the indices plus tooth staining index are recorded after 1 and 4 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302241081N7**
Registration date: **2014-09-14, 1393/06/23**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-09-14, 1393/06/23

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

Deputy of research and technology, Guilan University of Medical Sciences

Expected recruitment start date

2013-04-09, 1392/01/20

Expected recruitment end date

2013-06-10, 1392/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Green Tea Mouthwash Containing 1 % Tannin on Plaque, Gingivitis and tooth staining

Public title

Effect of green tea Mouthwash on Gingival inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Adult subjects with age range of 18-25; Systemically healthy; having mild to moderate gingivitis; having gingival index score of 1 at baseline; having at

least 20 standing teeth. Exclusion criteria: Having periodontal pocket ; having clinical attachment loss; being under medication; smoking; mouth breathing,; severe tooth crowding; wearing orthodontic appliances ; having any type of dental prostheses.

Age

From **18 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences

Street address

Opposite Sepah Bank, Vest Beheshti Blv.

City

Rasht

Postal code

4193893345

Approval date

2013-02-19, 1391/12/01

Ethics committee reference number

3910396406

Health conditions studied

1

Description of health condition studied

Chronic Gingivitis

ICD-10 code

K05.1

ICD-10 code description

Chronic gingivitis

Primary outcomes

1

Description

stain severity index

Timepoint

Baseline, 1, and 4 weeks

Method of measurement

Stain index, Lobene, 1968

2

Description

Gingival bleeding index

Timepoint

Baseline, 1, and 4 weeks

Method of measurement

Gingival Bleeding Index (Ainamo & Bay, 1975)

3

Description

Gingival Index

Timepoint

Baseline, 1, and 4 weeks

Method of measurement

Gingival Index (Loe & Silness, 1963)

4

Description

Stain extent index

Timepoint

Baseline, 1, and 4 weeks

Method of measurement

Stain index, Lobene, 1968

5

Description

Plaque Index

Timepoint

Baseline, 1, and 4 weeks

Method of measurement

Plaque Index: Turskey Modification of Quigley Hein

Secondary outcomes

1

Description

Decrease in plaque index

Timepoint

1 and 4 weeks after intervention

Method of measurement

Plaque Index: TMQH

2

Description

Decrease in gingival bleeding index

Timepoint

1 and 4 weeks after intervention

Method of measurement

Gingival Bleeding Index: Ainamo & Bay

3

Description

Decrease in Gingival Index

Timepoint

1 and 4 weeks after intervention

Method of measurement

Gingival Index: Loe & Silness

Intervention groups

1

Description

The intervention group use green tea mouthwash containing 1% Tannin

Category

Treatment - Drugs

2

Description

The control group use 0.1% chlorhexidine mouthwash

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry Guilan University of Medical Sciences

Full name of responsible person

Dr. Golpar Radafshar

Street address

Faculty of Dentistry, further than Khazar restaurant, Pro. Samiei Blv. Gaz Square

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Susan Komaie

Street address

Opposite Sepah band, West Shahid Beheshti Blv. Gaz Square

City

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Guilan University of Medical Sciences

Full name of responsible person

Nastaran Mirfarhadi

Position

MS Nursing education

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Dentistry, Guilan University of Medical Sciences

Full name of responsible person

Dr. Golpar Radafshar

Position

Associate Professor of Periodontology/ Head of Dental and Maxillofacial developmental disease research

Other areas of specialty/work

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Person responsible for updating data

Contact

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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