

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation the effect of Magnolia mouthwash on the levels of *S. mutans* in dental plaque and on the Plaque Percent Index

Protocol summary

Summary

Objective: This study aims to evaluate the effect of Magnolia Grandiflora bark mouth-wash on prevalence of Streptococcus mutans in dental plaque. **Materials and Methods:** In this crossover study, initially an aqua-ethanol extract of Magnolia Grandiflora bark will be obtained. Using a standard strain of *S. mutans* (ATCC 35668), the MIC of the Magnolia extract will be determined. In concordance with the MIC concentration, a mouthwash will be provided from the extract. Twenty volunteers will be entered the study to use this mouthwash and a placebo in crossover arrangements in case and control groups respectively. The prevalence of *S. mutans* will be measured in certain volume of volunteer's dental plaque at the beginning of the project (phase 1), after the first prescription (phase 2), following the wash out period (phase 3) and finally after the second prescription (phase 4) by culture on bacteriology media including blood agar and Mitis Bacitracin Salivarius Agar. Also the Plaque Percent Index will be calculated at each phase.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071518487N1**

Registration date: **2015-01-22, 1393/11/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-01-22, 1393/11/02

Registrant information

Name

Fateme Ghorbani

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Shahed University

Expected recruitment start date

2014-02-09, 1392/11/20

Expected recruitment end date

2014-04-09, 1393/01/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Magnolia mouthwash on the levels of *S. mutans* in dental plaque and on the Plaque Percent Index

Public title

The Effect of Magnolia mouthwash on dental caries and periodontal diseases

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Ages 18 to 35; Absence of systemic disease Exclusion criteria: Consumption of antibiotics from one month prior to the study; Active dental caries

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

All participants will be asked not to change their usual methods for their oral and dental health. With regards to their oral health status, all participants will be classified into two groups of moderate health (A) and poor health (B) based on the standard table for initial assessment of caries risk and the Plaque Percent Index.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahed University

Street address

ethics committee, Deputy Research, Shahedtehran
Dental Faculty, NO39, Italia Street, Keshavarz
Boulevard

City

Tehran

Postal code

Approval date

2014-01-25, 1392/11/05

Ethics committee reference number

41/191668

Health conditions studied

1

Description of health condition studied

Dental caries and Periodontal disease

ICD-10 code

K02, K05

ICD-10 code description

K02:Caries limited to enamel,dentin,cementume,
K05:Gingivitis and periodontal diseases

Primary outcomes

1

Description

The quantity of Streptococcus mutans in dental plaque

Timepoint

Before the study, a week after the first intervention, a week after the rest period, a week after the second intervention

Method of measurement

Bacterial counts

2

Description

Plaque Index Percentage

Timepoint

Before the study, a week after the first intervention, a week after the rest period, a week after the second intervention

Method of measurement

Plaque staining on dental surfaces and using standard formula for measuring Plaque Index Percentage

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Using Magnolia mouthwash, Volume: 15 cubic centimeters for each use, duration: One week after the last meal before bed every night, Method: 30 seconds of turning the mouthwash in the mouth

Category

Treatment - Drugs

2

Description

Control group: Using Placebo, Volume: 15 cubic centimeters for each use, duration: One week after the last meal before bed every night, Method: 30 seconds of turning the Placebo in the mouth

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

DR Saied Amel Jamehdar

Street address

Microbiology Department, Central Laboratory, Imam

Reza Hospital, Taghi Abad Square
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Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Dr Roza Haghgoo

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NO 39, Italia Street, Keshavarz Bulvard, Shahed
Dentistry School

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahed University

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

Shahed University

Full name of responsible person

Roza Haghgoo

Position

Associate professor in Pediatric Dentistry

Other areas of specialty/work

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Person responsible for updating data

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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