

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of grapeseed extract mouthwash on streptococcus mutans growth and gingival health

Protocol summary

Study aim

The aim of this study is evaluation of grapeseed extract mouth wash on streptococcus mutans growth and gingival health.

Design

Dental students voluntary participated to study are divided into two equal groups. By selecting the code blindly, they entered the mouthwashes and control group (water). The researcher is also unaware of the type of mouthwash and placebo and prescribes it as a code.

Settings and conduct

The study will be conducted in the dental faculty of Hamadan Dental Students on a three-blinded basis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy dental students with informed consent
Exclusion criteria: Systemic disease, drug use, periodontal disease and pregnancy

Intervention groups

Intervention group receive mouth wash containing of grapeseed extract. Control group receive water.

Main outcome variables

Reduction of carious bacteria growth, gingival inflammation, plaque index and bleeding on probing.

General information

Reason for update

In according to reference study duration reduced from 30 days to 15 days.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191225045891N3**
Registration date: **2020-03-11, 1398/12/21**
Registration timing: **prospective**

Last update: **2020-07-14, 1399/04/24**

Update count: **1**

Registration date

2020-03-11, 1398/12/21

Registrant information

Name

Fatemeh Ahmadi-Motamayel

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1059

Email address

f.ahmadi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-02, 1399/01/14

Expected recruitment end date

2021-04-03, 1400/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of grapeseed extract mouthwash on streptococcus mutans growth and gingival health

Public title

The effect of grapeseed extract mouthwash on oral health

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy dental students with informed consent

Exclusion criteria:

Systemic disease Drug taking Gingival and periodontal

diseases Pregnancy

Age
From **20 years** old to **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description
participants, principle investigator, healthcare providers and data analyses are blinded

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hamadan University of Medical Sciences

Street address
Shahid Fahmideh

City
Hamadan

Province
Hamadan

Postal code
6517838677

Approval date
2020-01-10, 1398/10/20

Ethics committee reference number
IR.UMSHA.REC.1398.882

Health conditions studied

1

Description of health condition studied
Gingival health

ICD-10 code
K02

ICD-10 code description

Dental caries

Primary outcomes

1

Description
Gingival health

Timepoint
Before intervention and 15 day after mouth wash using

Method of measurement
Observational

Secondary outcomes

1

Description
Plaque accumulation

Timepoint
efore and 1 month after intervention

Method of measurement
Oral disclosing tablets

Intervention groups

1

Description
Intervention group: 40 dental student voluntary selected and receive grapeseed extract mouth washes. Two file filled for all students. one before and one 15 day after intervention. Each persons used mouth washes 2 times a day for 1 minutes. Files consist: biographic data, bleeding on probing, gingival index and plaque accumulation

Category
Prevention

2

Description
Control group: 40 students only receive water.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Hamadan Dental School

Full name of responsible person
Fatemeh Ahmadi-Motamayel

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Saeed Bashirian
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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

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Fateme Ahmadi-Motamayel
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Person responsible for updating data

Contact

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Person responsible for general inquiries

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Not applicable

Data Dictionary

Not applicable