Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Clinical trial comparing the effect of standard toothpaste and herbal toothpaste containing berberine and saponin on dental plaque, gingival inflammation, and salivary bacterial count

Protocol summary

Study aim

To compare the effect of standard toothpaste and herbal toothpaste containing berberine and saponin on dental plaque, gingival inflammation, and salivary bacterial count

Design

Two-arm parallel-group, randomized, non-blinded trial in phase 2 incorporating 60 participants. A table of random numbers will be used for randomization.

Settings and conduct

The study is conducted in the School of Dentistry of Birjand University of Medical Sciences. After the correct manner of brushing is taught to them, one group uses standard toothpaste and the other group uses herbal toothpaste for 7 months.

Participants/Inclusion and exclusion criteria

Major inclusion criteria: Having a minimum of 24 teeth and non-consumption of antibiotics from 2 weeks before saliva sampling. Exclusion criteria: The presence of systemic problems such as diabetes and the presence of cavities

Intervention groups

Intervention group 1 (standard toothpaste): After the correct manner of brushing is trained to them, participants will brush their teeth twice daily for 3-5 minutes for a period of seven months using the classic Crest toothpaste. Intervention group 2 (Herbal toothpaste): After the correct manner of brushing is trained to them, participants will brush their teeth twice daily for 3-5 minutes for a period of seven months using the herbal toothpaste containing berberine and saponin.

Main outcome variables

dental plaque, gingival inflammation, and salivary bacterial count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170316033099N13**
Registration date: **2021-05-02, 1400/02/12**
Registration timing: **prospective**

Last update: **2021-05-02, 1400/02/12**
Update count: **0**

Registration date

2021-05-02, 1400/02/12

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3239 5680

Email address

roozgar@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical trial comparing the effect of standard toothpaste and herbal toothpaste containing berberine and saponin on dental plaque, gingival inflammation, and salivary bacterial count

Public title
The effect of herbal toothpaste containing berberine and saponin on oral and dental health

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Having a minimum of 24 teeth Signing informed consent form for participation in the study Non-consumption of antibiotics from 2 weeks before saliva sampling

Exclusion criteria:
Presence of systemic problems such as diabetes Presence of cavities

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Each participant will be assigned a code between 1 and 60. They will be allocated to intervention group 1 or intervention group 2 using the table of random numbers.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Birjand University of Medical Sciences

Street address
Ghaffari Ave.

City
Birjand

Province
South Khorasan

Postal code
9717853577

Approval date
2021-02-13, 1399/11/25

Ethics committee reference number
IR.Bums.Rec.1399.543

Health conditions studied

1

Description of health condition studied
Oral and dental health

ICD-10 code
K05

ICD-10 code description
Gingivitis and periodontal diseases

Primary outcomes

1

Description
dental plaque

Timepoint
baseline, months 3, 5, and 7 after baseline

Method of measurement
Plaque Index

2

Description
gingival inflammation

Timepoint
baseline, months 3, 5, and 7 after baseline

Method of measurement
Gingival Index

3

Description
Lactobacillus and Streptococcus mutans bacteria

Timepoint
baseline, months 3, 5, and 7 after baseline

Method of measurement
saliva swab

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 (standard toothpaste): After the correct manner of brushing is trained to them, participants will brush their teeth twice daily for 3-5 minutes for a period of seven months using the classic

Crest toothpaste.

Category

Prevention

2

Description

Intervention group 2 (Herbal toothpaste): After the correct manner of brushing is trained to them, participants will brush their teeth twice daily for 3-5 minutes for a period of seven months using the herbal toothpaste containing berberine and saponin.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Dr Mohammadreza Mofateh

Street address

Ghaffari Ave.

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3242 5402

Email

drmofatteh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Tooba Kazemi

Street address

Ghaffari Ave.

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3238 1200

Email

drtooba.kazemi@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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 general inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr. Hamid Ahmadi

Position

Dentist

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Ghaffari St.,

City

Birjand,

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3238 1708

Fax

Email

hamid.ahmd.97@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr. Zoya Tahergorabi

Position

Assoicate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

Street address

Ghaffari St.,

City

Birjand,

Province

South Khorasan

Postal code
9717853577
Phone
+98 56 3239 5680
Fax
Email
z.tahergorabi@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Mohammad Bagher Roozgar
Position
Translator
Latest degree
Master
Other areas of specialty/work
Others
Street address
Ghaffari St.,
City
Birjand,
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3239 5680
Fax
+98 56 3242 0447
Email
roozgar@bums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Deidentified Individual Participant Data Set
When the data will become available and for how long
After the paper extracted from the project is published and for 6 months
To whom data/document is available
Researchers
Under which criteria data/document could be used
Research purposes
From where data/document is obtainable
Personal correspondence with the corresponding author
What processes are involved for a request to access data/document
Email
Comments