Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of ginger mouthwash on plaque index and gingival index : A randomized double_- blind clinical trial

Protocol summary

Study aim
Evaluation of the effect of ginger mouthwash on plaque index and gingival index

Design
A randomized double_- blind parallel group with control group clinical trial on 50 participants . Balance block randomization technique was used.

Settings and conduct
All people are given a type of signal brand fluoride toothpaste, a type of toothbrush and mouthwash of the respective group in a dark plastic by someone other than the examiner so that people are not aware of the difference between mouthwashes. People are taught to brush twice a day with a modified bass method for 3 minutes, twice a day to use mouthwash for one minute for two weeks. They are asked to refrain from using other oral hygiene aids during these two weeks. Once at the beginning of the work, once on the 7th day of the intervention and once on the 14th day, the study is evaluated and recorded. These evaluations are performed in the Periodontology Department of Qazvin Dental School.

Participants/Inclusion and exclusion criteria
Inclusion criteria are: 18- to 45-year-olds who have at least 20 healthy teeth and, in terms of periodontal status, do not have periodontal disease and do not have a salcus deeper than 3 mm at any point. Criteria for non-inclusion in the study include: Systemic diseases affecting oral health such as diabetes, hypertension, thyroid disease, patients with a history of oral and gingival surgery, pregnant and lactating women, taking anticholinergic and antihypertensive and anti-hypertensive drugs. Depression, a history of radiotherapy and the use of intraoral devices such as orthodontic plates.

Intervention groups
Group A : Zingiber mouthwash Group B : Chlorhexidin mouthwash

Main outcome variables
Plaque Index / Gingival Index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220621055244N1**
Registration date: **2022-07-04, 1401/04/13**
Registration timing: **prospective**

Last update: **2022-07-04, 1401/04/13**
Update count: **0**

Registration date
2022-07-04, 1401/04/13

Registrant information

Name
Shabnam Haftani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 7734 8984

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2022-08-05, 1401/05/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title

Evaluation of the effect of ginger mouthwash on plaque index and gingival index : A randomized double_- blind clinical trial

Public title

Evaluation of the effect of ginger mouthwash on plaque index and gingival index

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Students of Qazvin University of Medical Sciences in the age range of 18-45 years Having 20 teeth at least Having no periodontal diseases Not having pocket depth more than 3 mm

Exclusion criteria:

Having systemic diseases affecting oral health such as diabetes , hypertension, thyroid diseases Having the history of periodontal or oral surgeries Pregnant or milch womens Taking anticholinergic, antihypertensions, antidepressant drugs and history of radiotherapy Using intraoral devices such as orthodontics appliences

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The 50 participants of the study are divided into two groups A and B using random allocation software using random block method. The size of each block is 5 and the total number of blocks is 10.Balanced random allocation method for participants in a randomized clinical trial study is used to evaluate the effect of two mouthwashes of ginger and chlorhexidine on PI and GI in 2 weeks.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants do not know about the difference between mouthwashes. Researcher and the examiner do not know that each person belongs to which group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Commite of Qazvin University of Medical Sciences

Street address

Deputy o Research and Technology , The first sub , Mavedat Alley , Shahid Beheshti Boulvard

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Province

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Postal code

3415613911

Approval date

2022-07-22, 1401/04/31

Ethics committee reference number

IR.QUMS.REC.1401.078

Health conditions studied

1

Description of health condition studied

Plaque Index / Gingival Index

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Plaque Index and Gingival Index

Timepoint

Once at the beginning of the work, once on the 7th intervention day and once on the 14th intervention day

Method of measurement

The plaque index is identified at each stage using a fuchsin tablet that is chewed in the mouth for 1 minutes. This index is measured in accordance with the Quigley-Hein Turesky modification index. In this way, the buccal and lingual (palatal) surfaces of all teeth are first obtained according to the following numbers and their average is considered as the index of each tooth. By summing the indices of all teeth and dividing them by the number of teeth, the plaque index in the patient is calculated. Based on the number of license plates, one of the following six points is considered for each level:Score zero: the surface is without plates. Score 1: Plaque should be scattered in the cervical part of the tooth. Score 1: The plaque should be in the form of a thin continuous line with a maximum thickness of 1 mm in the cervical tooth. Score 1: Plaque more than 2 mm thick but less than one third of the tooth crown is covered.

Score 1: The plaque is more than one third thick but less than two thirds of the tooth crown. Score 2: Plaque covers two-thirds or more of the tooth crown.The gingival index is recorded by the examiner by observing the appearance of the gingiva and also by using the Williams probe. The loe & silness method is used to examine the gingival index (Gingival index GI). The gingiva of each tooth are divided into 4 parts: mesiobuccal papilla, distobuccal papilla, midbuccal gingival margin and midlingual gingival margin and then evaluated and based on the results obtained, they are given one of the following four points:Score 0: If the gingiva have a normal appearance and are free of inflammation and bleeding. Score 1: low inflammation, slight discoloration, low edema, no bleeding during probing. Probing. Score 3: Severe inflammation, marked redness, edema and hypertrophy, ulcers and spontaneous bleeding. To achieve the GI of each tooth, the average GI of all surfaces of that tooth is considered, and to achieve the total oral GI, the average GI of all the examined teeth is considered.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Use ginger mouthwash twice a day for one minute for two weeks. Vi one Ginger mouthwash contains deionized water, ginger extract, glycerin, polyethylene glycol 40, xylitol, potassium sorbate, ploxamer 407, citric acid, menthol, sodium saccharin

Category
Prevention

2

Description
Control group: Use Chlorhexidine mouthwash twice a day for one minute for two weeks. Chlorhexidine mouthwash 0.2% vi One contains deionized water, sorbitol, glycerin, polyethylene glycol, xylitol, polysorbate 20, ploxamer 407, citric acid, menthol, chlorhexidine digluconate 0.2%, essential oil

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Qazvin University of Medical Sciences

Full name of responsible person
Shabnam Haftani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Dr Mehdi Mirhashemi

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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
Qazvin 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

Qazvin University of Medical Sciences
Full name of responsible person
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Position
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Latest degree
A Level or less
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available