

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluation of the effect of two mouthwashes: Tea tree oil \_ Alvoevera and Chlorhexidine 0/2 % on Salivary PH level

#### Protocol summary

##### Study aim

Evaluation of effect of Tea tree oil and Alvoevera mouthwash on Salivary PH level

##### Design

Crossover clinical trial, random assignment of 20 participants to 10 dual blocks, phase 3, random allocation software was used for randomization.

##### Settings and conduct

Qazvin dental students will enter the study if they are eligible. First, pH of the patient's non-stimulatory saliva is measured. Then, patient's PH of the saliva is measured after rinsing 20 ml of orange juice in the mouth for one minute. Then, patients are randomly divided into two equal groups by random block method and both groups receive interventions in a crossover design. After each intervention, salivary pH measurements are repeated immediately and 20 minutes later. No blinding is performed in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: students of the Faculty of Dentistry of Qazvin University of Medical Sciences in the age range of 25-18 years. Exclusion criteria: systemic diseases affecting saliva such as diabetes, hypertension, thyroid disease; smoking and drug abuse; Taking anticholinergic, antihypertensive, antidepressants; history of radiotherapy; use of Intraoral appliance as orthodontic device.

##### Intervention groups

First Intervention group : First, 20 ml of orange juice is rinsed in the mouth for one minute and then the tea tree oil - aloe vera irsha mouthwash is rinsed in the mouth for one minute. After 72 hours of wash out, the 0.2% Irsha chlorhexidine mouthwash is rinsed in the mouth for one minute. Intervention group 2: First, 20 ml of orange juice is rinsed in the mouth for one minute and then chlorhexidine 0.2% Irsha mouthwash is rinsed in the mouth for one minute. After 72 hours of wash out, the Aloe Vera Irsha Tea Tree Oil mouthwash is rinsed in the mouth for one minute.

#### Main outcome variables

Salivary pH

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211104052964N1**

Registration date: **2022-05-14, 1401/02/24**

Registration timing: **prospective**

Last update: **2022-05-14, 1401/02/24**

Update count: **0**

##### Registration date

2022-05-14, 1401/02/24

##### Registrant information

##### Name

Fatemeh Vahdat Bivarzani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 28 3256 6445

##### Email address

f.vahdatbivarzani@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-26, 1401/03/05

##### Expected recruitment end date

2022-07-21, 1401/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of two mouthwashes: Tea tree oil \_ Aloe vera and Chlorhexidine 0/2 % on Salivary PH level

**Public title**

Evaluation of effect of mouthwashes on Salivary PH level

**Purpose**

Basic science

**Inclusion/Exclusion criteria****Inclusion criteria:**

Dentistry students of Qazvin University of Medical Sciences in the age range of 18-25 years

**Exclusion criteria:**

Having systemic diseases affecting saliva such as diabetes, hypertension and thyroid diseases Smoking and drugs abuse Taking anticholinergic, antihypertensive, antidepressant drugs History of radiotherapy Using intraoral devices such as orthodontic appliance

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **6**

This study includes 20 participants and saliva will be collected from each participant 6 times. Thus: 1- PH of saliva of participants at the beginning of work 2- PH of saliva after rinsing 20 ml of orange juice 3- PH of saliva immediately after rinsing 1 minute 5 ml of the first mouthwash 4-PH of saliva 20 minutes after that 5-PH of saliva immediately after rinsing 1 minute 5 ml of the second mouthwash 6-PH of saliva 20 minutes after that

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The 20 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 2 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 tea tree oil and aloe vera and chlorhexidine on saliva pH.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Crossover

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Qazvin University of Medical Sciences

**Street address**

Deputy of research and technology ,The first sub,Mavedat Alley, Shahid Beheshti Boulevard

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3415613911

**Approval date**

2021-09-15, 1400/06/24

**Ethics committee reference number**

IR.QUMS.REC.1400.261

**Health conditions studied****1****Description of health condition studied**

salivary Ph

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

PH level of saliva

**Timepoint**

Saliva pH is measured at the beginning of the study and after orange juice and immediately and 20 minutes after using mouthwashes.

**Method of measurement**

Digital PH Meter Device

**Secondary outcomes**

empty

**Intervention groups****1****Description**

First intervention group: participants rinse 5 milliliter of Irsha Tea Tree Oil \_ Aloe Vera Mouthwash, which contains Poloxamer 407, Isopropyl myristate,Thymol, Sorbitol, Menthol, Eucalyptus, Tea Tree Oil, Aloe Vera , Xylitol, Authorized Cosmetic Essential Oil, Sorbate, Thymol ,

Sodium benzoate, Potassium sorbate, Citric acid, Cetylpyridinium chloride, Sodium fluoride, Color CL.42090, CL.19140 and Deionized water once in their mouth for 1 minute. After 72 hours of wash out, participants rinse 5 milliliter of Irsha chlorhexidine 0.2% mouthwash which contains chlorhexidine digluconate, xylitol, Cetylpyridinium chloride, menthol, citric acid, deionized water, polysorbate , color CL.16035 and color CL.17200- once in their mouth for 1 minute.

**Category**

Treatment - Drugs

**2****Description**

Second Intervention group: participants rinse 5 milliliter of Irsha chlorhexidine 0.2% mouthwash which contains chlorhexidine digluconate, xylitol, Cetylpyridinium chloride, menthol, citric acid, deionized water, polysorbate , color CL.16035 and color CL.17200- once in their mouth for 1 minute. After 72 hours of wash out, participants rinse 5 milliliter of Irsha Tea Tree Oil \_ Aloe Vera Mouthwash, which contains Poloxamer 407, Isopropyl myristate,Thymol, Sorbitol, Menthol, Eucalyptus, Tea Tree Oil, Aloe Vera , Xylitol, Authorized Cosmetic Essential Oil, Sorbate, Thymol , Sodium benzoate, Potassium sorbate, Citric acid, Cetylpyridinium chloride, Sodium fluoride, Color CL.42090, CL.19140 and Deionized water once in their mouth for 1 minute.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Qazvin University of Medical Sciences

**Full name of responsible person**

Fatemeh Vahdat Bivarzani

**Street address**

School of Dentistry, Qazvin University of Medical Sciences, Shahid Bahonar Blvd, Qazvin

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3415759811

**Phone**

+98 28 3256 6445

**Fax**

+98 28 3335 3066

**Email**

dentfaculty@qums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr.Mehdi Mirhashemi

**Street address**

Deputy of research and technology ,The first sub,Mavedat Alley, Shahid Beheshti Boulevard

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3415613911

**Phone**

+98 28 3336 8124

**Fax**

+98 28 3335 0056

**Email**

researchdpt@qums.ac.ir

**Web page address**

https://vcr.qums.ac.ir

**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**

Fatemeh Vahdat Bivarzani

**Position**

Collegian

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

**Street address**

First floor, number 5, Golbarg 6 alley, Rangin kaman street, 3rd area, mohammadiyeh

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3491941359

**Phone**

+98 28 3256 6445

**Fax****Email**

f.vahdatbivarzani@qums.ac.ir

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Fatemeh Vahdat Bivarzani

**Position**

Collegian

**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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**Phone**

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**Fax****Email**

f.vahdatbivarzani@qums.ac.ir

## Person responsible for updating data

**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Fatemeh Vahdat Bivarzani

**Position**

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**Latest degree**

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**Fax****Email**

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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