

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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)

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+98 28 3256 6445

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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

AgeFrom **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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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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