

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparison of the effectiveness of shallomin II and chlorhexidine mouthwashes in treating plaque induced gingivitis: A clinical trial and microbiologic study

Protocol summary

Study aim

Comparison of the effectiveness of shallomin II and chlorhexidine mouthwashes in treating plaque induced gingivitis: A clinical trial and microbiologic study

Design

The study is a parallel double-blind study. Randomization and assignment of patients to each of the two groups is done by the nurse. Two mouthwashes in the same packaging are offered to 36 patients, and the patients, presenters, and students are not aware of the type of mouthwash. The data will be analyzed by SPSS software version 22.

Settings and conduct

36 patients with gingivitis referred to the periodontology department of the Faculty of Dentistry, Jundishapur University of Medical Sciences, Ahvaz

Participants/Inclusion and exclusion criteria

1. Systemically healthy 2. The presence of more than 20 permanent teeth (except the third molar) 3. Untreated gingivitis (probing depth less than equal to 3, no clinical attachment loss, no evidence of radiographic bone loss.) 4. The percentage of areas with bleeding during probing should be more than 30%. 5. Not using antibiotics and anti-inflammatory drugs in the last three months 6. Not using any mouthwash in the last month. 7. Not using fixed orthodontic devices or prosthetics that interfere with the evaluation. 8. Not using cigarettes and alcohol 9. Do not have mental retardation 10. Do not be pregnant or breastfeeding. Exclusion criteria 1. Allergy to chlorhexidine and Shalomin II 2. Any pathology in the oral mucosa 3. Acute gingivitis

Intervention groups

Shalomin II herbal mouthwash: mouthwash derived from Iranian shallot, 5 ml twice a day for 30 seconds each time for two weeks Chlorhexidine mouthwash 0.2%: 5 ml each time and twice a day for 30 seconds each time for two weeks.

Main outcome variables

Plaque Index(Loe & Sillness): Gingival index(Sillness & loe) :Total colony count

General information

Reason for update

Editing indicators and entry criteria.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230305057627N1**

Registration date: **2023-04-17, 1402/01/28**

Registration timing: **prospective**

Last update: **2023-10-16, 1402/07/24**

Update count: **1**

Registration date

2023-04-17, 1402/01/28

Registrant information

Name

Neda Samie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3320 5168

Email address

samie-n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-05-22, 1402/03/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of shallomin II and chlorhexidine mouthwashes in treating plaque induced gingivitis: A clinical trial and microbiologic study

Public title
Comparison of the effectiveness of shallomin II and chlorhexidine mouthwashes in treating plaque induced gingivitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Systemically healthy The presence of more than 20 permanent teeth (except the third molar) Untreated gingivitis (probing depth less than equal to 3, no clinical attachment loss, no evidence of radiographic bone loss.) The percentage of areas with bleeding during probing should be more than 30% Not using antibiotics and anti-inflammatory drugs in the last three months No mouthwash has been used in the past month Do not use cigarettes or alcohol Do not have mental retardation Not during pregnancy or breastfeeding
Exclusion criteria:
 The presence of any pathology in the oral mucosa Acute gingivitis

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study the randomization will be done using random numbers table. After consultation with the statistics specialist even numbers will be considered for the intervention group and odd numbers for control group. The researcher stays on one of the numbers then the right direction which predefined to move and the numbers will be registered.

Blinding (investigator's opinion)
Double blinded

Blinding description
Shallomin mouthwash will be made with the taste and color of used chlorhexidine mouthwash. Both mouthwashes are put in the same bottles and coded

(code 1 and 2). All coded bottles are placed in exactly the same packaging. The examiner will give each patient a package without knowing the meaning of each code and the type of bottle in each package, and after opening the package, the bottle code of each patient will be noted. During the study, the examiner and the patients will not know the type of mouthwash used. Meanwhile, patients are aware of participating in the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Jundishapur University, Golestan, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

1579461357

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.AJUMS.REC.1401.519

Health conditions studied

1

Description of health condition studied

gingivitis

ICD-10 code

K05.10

ICD-10 code description

Chronic gingivitis, plaque induced

Primary outcomes

1

Description

Gingival Index (Sillness & loe)

Timepoint

At the beginning of study, seventh day and fourteenth day

Method of measurement

Using a periodontal probe

2

Description

Plaque Index (Loe & Sillness)

Timepoint

At the beginning of study, seventh day and fourteenth day

Method of measurement

Using a periodontal probe

3

Description

Total colony count

Timepoint

At the beginning of study, seventh day and fourteenth day

Method of measurement

Counting and recording

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 18 patients should use Shallomin II mouthwash twice a day for 2 weeks, each time at 5 cc for 30 seconds, and avoid eating and drinking for 30 to 45 minutes. The patient is also taught the correct method of brushing and hygiene education.

Category

Treatment - Drugs

2

Description

Intervention group: 18 patients should use 0.2% chlorhexidine mouthwash twice a day for 2 weeks, each time at 5 cc for 30 seconds, and avoid eating and drinking for 30 to 45 minutes. The patient is also taught the correct method of brushing and hygiene education.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Jundishapur Dental School

Full name of responsible person

Neda Samie

Street address

Dental School, Dey Ave, Golestan Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehrnoosh Zakerkish

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Reza Kaviani Nezhad

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

Part of the data, such as information about the main outcome, can be shared.

When the data will become available and for how long

Access starts 6 months after the results are published.

To whom data/document is available

Only for researcher working in academic and scientific institutions

Under which criteria data/document could be used

There are no conditions and all colleagues can use all the data

From where data/document is obtainable

Reza Kaviani Nezhad, Email adress:
rezakv999@gmail.com

What processes are involved for a request to access data/document

Finally one week after requesting data or documentation

Comments