Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 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
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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

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Latest degree
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Person responsible for updating data

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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