Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effect of lemon verbena mouthwash on gingivitis in comparison with chlorhexidine: A clinical study

Protocol summary

Study aim
Evaluation of the effect of using lemon verbena mouthwash on microbial plaque and reduce gingivitis

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients, randomized

Settings and conduct
A total of 60 patients referred to Mashhad Dental School who are diagnosed with gingivitis will be included in the study. Blinding is done with the help of random numbers and specified code. Data analyzers and outcome assessors are blinded in this study. Patients are divided into three groups; The first group receives lemonade mouthwash, the second group receives chlorhexidine mouthwash and the third group receives placebo. All three groups use mouthwash twice a day for 10 cc each time for two weeks. On days 0 and 15 and 30, the indices were measured and the effect of lemon mouthwash on microbial plaque and reduction of gingivitis was determined by analyzing the data.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having an average gingival index of all teeth at least 1، average plaque index of all teeth at least 1، average probing depth of all teeth maximum 3mm، without clinical attachment loss Exclusion criteria: Pregnancy and lactation، Systemic diseases that cause generalized gingivitis، Lack of refer for follow-up، Lack of oral hygiene

Intervention groups
The first group receives lemonade mouthwash, the second group receives chlorhexidine mouthwash and the third group receives placebo. All three groups use mouthwash twice a day for 10 cc each time for two weeks.

Main outcome variables
gingival index, plaque index, bleeding index

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140817018834N10**
Registration date: **2021-07-13, 1400/04/22**
Registration timing: **prospective**

Last update: **2021-07-13, 1400/04/22**
Update count: **0**

Registration date
2021-07-13, 1400/04/22

Registrant information

Name
Nahid Nasrabadi

Name of organization / entity
Shahid Sadoughi University of Medical Sciences of Yazd

Country
Iran (Islamic Republic of)

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+98 35 1621 2623

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2021-10-22, 1400/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of lemon verbena mouthwash on gingivitis in comparison with chlorhexidine: A clinical study

Public title
Effect of lemon verbena mouthwash on gingivitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
average gingival index of all teeth at least 1 average plaque index of all teeth at least 1 average probing depth of all teeth maximum 3mm without clinical attachment loss

Exclusion criteria:
Pregnancy and lactation Systemic diseases that cause generalized gingivitis Lack of refer for follow-up Lack of oral hygiene

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is simple. Patients will be randomly divided into three groups using a table of random numbers. A random number is assigned to each group and the intervention is determined accordingly. Each patient is given a code. For blinding with the help of random numbers and specified code, the type of intervention is placed in the envelope. The type of intervention is the use of mouthwash (including chlorhexidine, lemon verbena and placebo). Necessary instructions and how to use are given to the patient.

Blinding (investigator's opinion)
Double blinded

Blinding description
The three mouthwashes used in the study are packaged in exactly the same plastic bottles.Therefore, these mouthwashes can be masked in terms of shape. Therefore, the study is performed unknowingly in two ways and the patient and the dentist (evaluator) are masked.The treatment protocol used in the pilot research project is as follows: The patient refers to the researcher (pharmacist) and is randomly assigned to one of the groups based on the codes. The researcher provides one of the mouthwashes to the patient based on the assigned code. The patient is referred to a study dentist and is prescribed by a dentist.After recording the results (efficiency), the results are provided to the person performing the data analysis (clinical pharmacist) in the form of code.Data analysis is performed without the knowledge of the person analyzing the type of mouthwash and the name of the patient, only based on the provided codes.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences_Mashhad faculty of dentistry

Street address
Mashhad faculty of dentistry, Vakil Abad Blv, Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948959

Approval date
2020-10-21, 1399/07/30

Ethics committee reference number
IR.MUMS.DENTISTRY.REC.1400.043

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, plaque index, bleeding index

Timepoint
The beginning of the study (before the intervention) and 15 and 30 days after the start

Method of measurement
View and use the probe

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 20 patients should use lemon verbena mouthwash twice a day for 10 weeks, each time at 10 cc for 30 seconds, and avoid eating and drinking for half an hour after eating. The patient is also taught the correct method of brushing and hygiene education.

Category
Treatment - Drugs

2

Description
20 patients should use 0.2% chlorhexidine mouthwash twice a day for 10 weeks, each time at 10 cc for 30 seconds, and avoid eating and drinking for half an hour after eating. The patient is also taught the correct method of brushing and hygiene education.

Category
Treatment - Drugs

3

Description
Control group: 20 patients should use placebo mouthwash twice a day for 10 weeks, each time at 10 cc for 30 seconds, and avoid eating and drinking for half an hour after eating. The patient is also taught the correct method of brushing and hygiene education.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad faculty of dentistry

Full name of responsible person
Nahid Nasrabadi

Street address
Mashhad of faculty of dentistry, Vakil Abad Blv, Mashhad, Razavi khorasan province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Vice Chancellor for research of Mashhad University of Medical Sciences

Street address
Deputy of Technology and Research, Qureshi building, next to Hoveyze cinema, Daneshgah Avenue.

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Nahid Nasrabadi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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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
Yes - There is 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
The data is related to the main consequence after unidentifiable people are shared
When the data will become available and for how long
6 month after printing the results.
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
If you are to submit a article to a journal, they will be asked to receive the data.
From where data/document is obtainable
Person responsible for scientific study.
nasran@mums.ac.ir
What processes are involved for a request to access data/document
Sending an email to the given address and waiting time to receive a response less than a month.
Comments