

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 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)

Phone

+98 35 1621 2623

Email address

nasran@mums.ac.ir

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

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nasran@mums.ac.ir

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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tafaghodim@mums.ac.ir

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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Person responsible for scientific inquiries

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Person responsible for updating data

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Web page address

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