Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of effectiveness of nigella sativa mouthwash with chlorhexidine mouthwash on improvement of gingivitis

Protocol summary

Study aim
Determining the comparison of the effectiveness of black seed mouthwash with chlorhexidine mouthwash in improving gingivitis

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, on 36 patients, simple random method will be used for randomization.

Settings and conduct
36 people aged 20 to 40 who referred to the Periodontology Department of Yazd Dental School will be divided into two groups of 18 people and one group will be given black seed mouthwash and the other group will be given chlorhexidine mouthwash. Both mouthwashes will be put in similar bottles, the contents of which are not known. In order to blind the researcher, the researcher who examines and performs the measurements will have no knowledge of the type of substance inside the bottles. We will explain to the participants to use 10 ml of prescribed mouthwash twice a day for 30 seconds. Bass modified method and flossing will also be taught to them.

Participants/Inclusion and exclusion criteria
Referees to the Periodontology Department of Yazd School of Dentistry

Intervention groups
People will be divided into two groups of 18 people and one group will be given black seed mouthwash and the other group will be given chlorhexidine mouthwash. The two groups will tried to be the same in terms of gender and age distribution.

Main outcome variables
Plaque index according to the O'Leary index plaque criterion; Bleeding index according to bleeding index criteria; Tooth color change according to stain index criteria

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221212056786N2**
Registration date: **2023-10-03, 1402/07/11**
Registration timing: **retrospective**

Last update: **2023-10-03, 1402/07/11**
Update count: **0**

Registration date
2023-10-03, 1402/07/11

Registrant information
Name
Seyed mohammad Arab farashahi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 35 3621 2222
Email address
sm.arab@ssu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-04-04, 1402/01/15
Expected recruitment end date
2023-05-20, 1402/02/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison of effectiveness of nigella sativa mouthwash with chlorhexidine mouthwash on improvement of gingivitis

Public title
Comparison of effectiveness of nigella sativa mouthwash with chlorhexidine mouthwash on improvement of gingivitis

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
No attachment loss Probing depth lower than 3 milimeters Under no orthodontics or prosthetic treatments Plaque index 1 or more in 60% areas At least 20 teeth Bleeding on probing in at least 30% of areas

Exclusion criteria:
Having a systemic disease Using antibiotics in the last 3 months Allergic to nigella sativa Using drugs affecting periodontium Lack of co-operation in the study Not using the mouthwash for 2 times

Age
From **20 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomly assign qualified people to two groups, the Random allocation software version 2 will be used, and the random allocation method will be also a simple random method. First, the first eligible person will get number 1, and then the eligible people will get number 36, and based on the random allocation done by the software, each person will receive medicine A or B. In order to blind the random allocation, the list of random allocation will be provided to another person who is not in the study and before the patient's visit based on the number, the individual's treatment group will be asked by the third person by phone or SMS.

Blinding (investigator's opinion)
Double blinded

Blinding description
Both mouthwashes will be put in similar bottles, the contents of which are not known. In order to blind the researcher, the researcher herself, who examines and performs the measurements, will have no knowledge of the type of substance inside the bottles.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Yazd University of Medical Sciences

Street address
Faculty of Dentistry, Imam Reza Blvd., Kharat Blvd., Daheh Fajr Blvd., Yazd

City
yazd

Province
Yazd

Postal code
8914881167

Approval date
2023-01-23, 1401/11/03

Ethics committee reference number
IR.SSU.DENTISTRY.REC.1401.078

Health conditions studied

1

Description of health condition studied
Gingivitis

ICD-10 code
K05

ICD-10 code description
Gingivitis and periodontal diseases

Primary outcomes

1

Description
Investigating gingivitis and tooth discoloration after using mouthwash

Timepoint
Examining gingivitis and tooth discoloration at the beginning of the study and after two weeks

Method of measurement
Examining the plaque index using the O'Leary index plaque criterion and bleeding index using the bleeding index criterion and tooth discoloration using the stain index criterion

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group is given Nigella sativa mouthwash. Patients are told to use 10 milliliters of mouthwash twice a day for 30 seconds for two weeks. The extract is obtained from a grocery in Yazd and used to produce mouthwash. Mouthwash is prepared with a concentration of 20%.

Category

Prevention

2

Description

Control group: This group is given chlorhexidine mouthwash. 0.2% chlorhexidine solution (Shahr Daru, Iran) is used twice a day, 10 ml each time, for 30 seconds for two weeks.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Periodontology, Faculty of Dentistry, Yazd

Full name of responsible person

seyed mohammad arab farashahi

Street address

Faculty of Dentistry, Imam Reza Blvd., Kharat Blvd., Daheh Fajr Blvd., Yazd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Seyed Mostafa Mahmoodi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Educational and research assistant of Shahid Sadoughi University of Medical Sciences, Yazd

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

Tabriz University of Medical Sciences

Full name of responsible person

seyed mohammad arab farashahi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

seyed mohammad arab farashahi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
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Position
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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
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
Yes - There is 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
Title and more details about the data/document
All data can be shared
When the data will become available and for how long
From February 2023 to 1 year after the publication of the article
To whom data/document is available
For all people, including those working in academic and scientific institutions and industry
Under which criteria data/document could be used
email and call
From where data/document is obtainable
mohammad arab farashahi, 09133735190, sma.farashahi_69@yahoo.com
What processes are involved for a request to access data/document
After sending the email, the data is transferred
Comments