

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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		Secondary Ids
		empty
Public title	Comparison of effectiveness of nigella sativa mouthwash with chlorhexidine mouthwash on improvement of gingivitis	Ethics committees
Purpose	Prevention	<u>1</u>
Inclusion/Exclusion criteria		Ethics committee
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	Name of ethics committee
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	Ethics Committee of Yazd University of Medical Sciences
Age	From 20 years old to 40 years old	Street address
Gender	Both	Faculty of Dentistry, Imam Reza Blvd., Kharat Blvd., Daheh Fajr Blvd., Yazd
Phase	N/A	City
Groups that have been masked	- Participant - Investigator	yazd
Sample size	Target sample size: 36	Province
Randomization (investigator's opinion)	Randomized	Yazd
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.	Postal code
Blinding (investigator's opinion)	Double blinded	8914881167
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.	Approval date
Placebo	Not used	2023-01-23, 1401/11/03
Assignment	Parallel	Ethics committee reference number
Other design features		IR.SSU.DENTISTRY.REC.1401.078
		Health conditions studied
		<u>1</u>
		Description of health condition studied
		Gingivitis
		ICD-10 code
		K05
		ICD-10 code description
		Gingivitis and periodontal diseases
		Primary outcomes
		<u>1</u>
		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
		<u>1</u>
		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

City

yazd

Province

Yazd

Postal code

8914881167

Phone

+98 35 3625 5881

Email

sma.farashahi_69@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Seyed Mostafa Mahmoodi

Street address

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

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yazd

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pajoheshdentalyazd@gmail.com

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

Street address

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

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yazd

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Email

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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

Dentistry

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Person responsible for updating data**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

Dentistry

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Province

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Email

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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