

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparing the effect of chlorhexidine mouthwash with kefir drink on clinical indices of gingivitis

Protocol summary

Study aim

Comparing the effect of chlorhexidine mouthwash with kefir drink on clinical indicators of gingivitis.

Design

A clinical trial with a control group with parallel groups, without the possibility of blinding, randomized by the random blocks, on 40 patients, random allocation software 2 will be used for randomization.

Settings and conduct

The location of the Periodontology Department of Mazandaran Dental School, explaining all the treatment steps and obtaining a written statement from the patients, measuring clinical parameters including PI, GI and SBI by a final year dental student on Ramfjord teeth, complete scaling and health education, division Classification into two test and control groups, delivery of mouthwashes to the patient, recording of indicators at the beginning of the study and at the end of the first and third week.

Participants/Inclusion and exclusion criteria

Entry requirements: People must have appropriate cooperation. People with plaque-related gingivitis; People with systemic disease, corticosteroid users and smokers. People with a history of antibiotic treatment in the last 3 months

Intervention groups

In this study, we will have two intervention groups. One group was given 5 ml of chlorhexidine mouthwash per day for 21 days, and the other group was given 100 ml of kefir mouthwash for 21 days.

Main outcome variables

PI index, GI index, SBI index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200905048620N2**

Registration date: **2024-02-09, 1402/11/20**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-09, 1402/11/20**

Update count: **0**

Registration date

2024-02-09, 1402/11/20

Registrant information

Name

Leila Jabbareh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3325 4134

Email address

l.jabbareh@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-08, 1402/11/19

Expected recruitment end date

2024-05-08, 1403/02/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of chlorhexidine mouthwash with kefir drink on clinical indices of gingivitis

Public title

Investigating the effect of kefir drink on gingivitis

Purpose

Supportive	Sari
Inclusion/Exclusion criteria	Province
Inclusion criteria:	Mazandaran
Patients who have appropriate cooperation Patients with at least 20 functioning teeth Patients with plaque-related gingivitis	Postal code
Exclusion criteria:	4815733971
People with systemic diseases People using corticosteroids and smoking People who are allergic to mouthwash Poorly cooperative people People have orthodontics and prostheses Pregnant people People with a history of antibiotic treatment or taking anti-inflammatory drugs in the last 3 months People with mouth breathing habit	Approval date
Age	2024-01-09, 1402/10/19
From 18 years old	Ethics committee reference number
Gender	IR.MAZUMS.REC.1402.551
Both	
Phase	
N/A	
Groups that have been masked	
No information	
Sample size	
Target sample size: 40	
Randomization (investigator's opinion)	
Randomized	
Randomization description	
Using random allocation software 2, patients are distributed into two control and intervention groups using the randomized block method (blocks of 4). The numbers of each block are placed in sealed envelopes. Then, according to the order of people's visits, an envelope is opened randomly and numbers are assigned to people. People with even numbers are assigned to the intervention group and people with odd numbers are assigned to the control group. This process is repeated until the last sample is selected.	
Blinding (investigator's opinion)	
Not blinded	
Blinding description	
Placebo	
Not used	
Assignment	
Parallel	
Other design features	
Secondary Ids	
empty	
Ethics committees	
1	2
Ethics committee	Description
Name of ethics committee	gingival sulcus bleeding index
Ethics Committee of Mazandaran University of Medical Sciences	Timepoint
Street address	At the beginning of the study (before using mouthwashes) and 7, 21 days after starting to use mouthwashes
Research Vice-Chancellor ., University Building No. 2., Moalem Square.,	Method of measurement
City	Examination and recording of gingival bleeding for each tooth by periodontal probe and Muhlemann & Son table

Intervention groups

1

Description

Intervention group: This group will be given 100 ml of kefir drink for 21 days. In this study, homemade kefir drink will be used (after boiling 1.5% fat milk of Pegah Dairy Company of Iran and cooling it at room temperature, kefir grains will be added, fermentation will be done at 48°C for 48 hours and then the kefir grains will be separated by filtering) and the patients will be taught to rinse their mouth twice a day for one minute for 3 weeks. Gargle the given. They will also be told to refrain from eating and drinking for half an hour and from consuming other probiotic products during the treatment period.

Category

Prevention

2

Description

Control group: This group will be given 0.2% chlorhexidine mouthwash made by Iran Najo Company in the amount of 5 ml per day for 21 days. Patients will be instructed to gargle the given mouthwash for one minute twice a day for 3 weeks.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Touba Dental Clinic

Full name of responsible person

Dr. Leila Jabareh

Street address

Touba Dental Clinic, Khazar Boulevard, Sari

City

Sari

Province

Mazandaran

Postal code

4816895475

Phone

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Email

l.jabbareh@mazums.ac.ir

Web page address

https://www.mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. pedram Ebrahim nejad

Street address

Touba Dental Clinic., Khazar Boulevard.

City

Sari

Province

Mazandaran

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Email

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Web page address

https://www.mazums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Leila Jabbareh

Position

PhD in periodontics

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Sari Dental clinic., next to Touba ., Caspian Square

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Province

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Email

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Web page address

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Person responsible for scientific inquiries

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Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Dr. Leila Jabareh
Position
PhD in periodontics
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Latest degree
Specialist
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Email

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

Undecided - It is not yet known if there will be 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

After finishing the project, the results will be delivered in the form of a final report and electronically (on a CD) to the Research Vice-Chancellor and Faculty of Dentistry of Mazandaran University of Medical Sciences.

When the data will become available and for how long

The decision regarding the access to the data will be the responsibility of the vice chancellor of research and the Faculty of Dentistry of Mazandaran University of Medical Sciences, as well as the supervisor.

To whom data/document is available

Vice chancellor of Research, Faculty of Dentistry, Mazandaran University of Medical Sciences and also a supervisor

Under which criteria data/document could be used

To submit the final report and write the article

From where data/document is obtainable

Vice chancellor of Research, Faculty of Dentistry, Mazandaran University of Medical Sciences and also a supervisor

What processes are involved for a request to access data/document

Written request to the research assistant or the school of Dentistry of Mazandaran University of Medical Sciences and obtaining the consent of the supervisor

Comments