Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 11 3325 4134

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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

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have appropriate cooperation Patients with at least 20 functioning teeth Patients with plaque-related gingivitis

Exclusion criteria:

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

Age

From **18 years** old

Gender

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

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Research Vice-Chancellor ., University Building No. 2., Moalem Square.,

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2024-01-09, 1402/10/19

Ethics committee reference number

IR.MAZUMS.REC.1402.551

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

dental plaque index

Timepoint

At the beginning of the study (before using mouthwashes) and 7 and 21 days after starting to use mouthwashes

Method of measurement

Observing and recording the plaque index of each tooth according to the Loe & Silness scale table

Secondary outcomes

1

Description

gingival index

Timepoint

At the beginning of the study (before using mouthwashes) and 7, 21 days after starting to use mouthwashes

Method of measurement

Examination and recording of gingival index for each tooth according to Loe & Silness scale table for gingival index

2

Description

gingival sulcus bleeding index

Timepoint

At the beginning of the study (before using mouthwashes) and 7, 21 days after starting to use mouthwashes

Method of measurement

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 It 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

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Mazandaran

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4816895475

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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.

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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
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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Web page address
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Person responsible for scientific inquiries

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

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Person responsible for updating data

Contact

Name of organization / entity
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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
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 Faculty 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