Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

The effect of probiotics in the treatment of patients with halitosis

Protocol summary

Study aim

Determining the effect of probiotics in the treatment of halitosis patients based on age Determining the effect of probiotics in the treatment of halitosis patients based on gender Determining the effect of probiotics in the treatment of halitosis patients based on the severity of halitosis Determining the effect of probiotics in the treatment of patients based on Organoleptic Determining the side effects of probiotics in the intervention group

Design

The study is a quasi-experimental intervention that has only one group with 47 patients who all undergo the same type of intervention

Settings and conduct

Demographic information is asked and recorded from adult patients with halitosis referring to Sari gastroenterology clinics after obtaining consent. All patients will receive the same treatment. The condition of halitosis is also evaluated during the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients between the ages of 18 and 60 years old with halitosis with an Organoleptic score of two and above, determined by the doctor and by the person himself. Exclusion criteria: infection of the nose and pharynx; sensitivity to probiotics; infection of the mouth and teeth; advanced renal failure; pregnancy and breastfeeding; Cirrhosis; used immunosupresive drugs; recent surgery; typical symptoms of reflux or peptic ulcer; antibiotic use in the last month

Intervention groups

Patients receive probiotic capsules every 12 hours. Open a capsule of Fami Lact and dissolve it in 50cc of water and gargle and swallow it once in the morning after breakfast and once at night before going to bed and after brushing your teeth. This method is used for one month.

Main outcome variables

The degree of change in mouth odor is recorded by the doctor and patient based on organoleptic

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200915048726N2**
Registration date: **2023-10-05, 1402/07/13**
Registration timing: **prospective**

Last update: **2023-10-05, 1402/07/13**
Update count: **0**

Registration date

2023-10-05, 1402/07/13

Registrant information

Name

Arash kazemi visri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3337 7176

Email address

arash_6z@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotics in the treatment of patients with

halitosis

Public title
The effect of synbiotics in the treatment of patients with halitosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range from 18 to 60 years Halitosis with an Organoleptic (OLT) score of two and above, which is subjectively determined by the doctor and objectively by the person herself Informed consent
Exclusion criteria:
The presence of infection and active inflammation of the nose and pharynx in examination and history History of sensitivity to probiotics The presence of infection and active inflammation of the mouth and teeth in examination and history Advanced renal failure Cirrhosis of the liver The patient's lack of consent to participate or the desire to withdraw from the study Use of immunosuppressive drugs Pregnancy and breastfeeding Use of mouthwash and mouth fresheners during the study Patients with typical symptoms GERD or peptic ulcer Use of antibiotics in the last month Recent surgery
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **47**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
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
Imam Khomeini Hospital, Razi St
City
sari
Province
Mazandaran
Postal code
4816633131
Approval date
2023-07-10, 1402/04/19
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1402.18236

Health conditions studied

1

Description of health condition studied
Halitosis
ICD-10 code
R19.6
ICD-10 code description
Halitosis

Primary outcomes

1

Description
Severity of halitosis
Timepoint
before treatment (day zero); Day 15; Day 30 (end of treatment); Day 45 and Day 60
Method of measurement
based on organoleptic score

Secondary outcomes

1

Description
Side effects
Timepoint
before treatment (day zero); Day 15; Day 30 (end of treatment)
Method of measurement
evaluation checklist

2

Description
Remission rate
Timepoint
before treatment (day zero); Day 15; Day 30 (end of treatment); Day 45 and Day 60
Method of measurement
based on organoleptic score

Intervention groups

1

Description
Intervention group: Patients who are eligible to

participate in the study will receive a diet of probiotic capsules every 12 hours. Open a Fami Lact capsule of Bio Fermentation Company and dissolve it in 50cc of water and gargle and swallowed it once in the morning after breakfast and once at night before going to bed and after brushing your teeth (the patient should not use mouthwash while studying)), this method is used for one month. All patients will be educated about potential side effects and will be monitored during treatment to assess for side effects, which are very uncommon, and for proper use. All patients are asked to record any side effects that occur during treatment, including diarrhea, constipation, dyspepsia, bloating, and skin rash. Severe side effects are defined as complications that disrupt daily activities and require the patient to stop treatment, which is very rare.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital - Sari
Full name of responsible person
Arash Kazemi
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Razi Street, Imam Khomeini Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Mazandaran University of Medical Sciences, Valiasr Highway, Joibar three ways, Imam Square
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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
Arash Kazemi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Others
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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
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data can be shared when participants are not identifiable
When the data will become available and for how long
Ability to access data 6 months after publishing the results
To whom data/document is available
The data will be available to academic researchers and non-academic physicians
Under which criteria data/document could be used
Perform other analyzes and extract more results
From where data/document is obtainable
Please refer to the e-mail address of the corresponding author
What processes are involved for a request to access data/document
Submit a request to the Deputy of research and technology of the University / Refer the request to the relevant author of the project
Comments