

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 immunosuppressive 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

Street address

Razi Street, Imam Khomeini Hospital

City

sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3337 4977

Fax

+98 11 3337 4977

Email

arash_6z@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Pedram Ebrahimnejad

Street address

Mazandaran University of Medical Sciences, Valiasr Highway, Joibar three ways, Imam Square

City

sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Phone

+98 11 3448 4800

Fax

+98 11 3448 4800

Email

pebrahimnejad@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

Arash Kazemi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Others

Street address

Razi Street, Imam Khomeini Hospital

City

sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3337 4977

Fax

+98 11 3337 4977

Email

arash_6z@yahoo.com

Person responsible for scientific 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
Street address
Razi Street, Imam Khomeini Hospital
City
sari
Province
Mazandaran
Postal code
4816633131
Phone
+98 11 3337 4977
Fax
+98 11 3337 4977
Email
arash_6z@yahoo.com
Web page address

Person responsible for updating data

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
Street address
Razi Street, Imam Khomeini Hospital
City
Sari
Province
Mazandaran
Postal code
4816633131
Phone

+98 11 3337 4977

Fax

+98 11 3337 4977

Email

arash_6z@yahoo.com

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