Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of Oral Probiotics on Symptoms in Patients with Treatment-Resistant Acute Anal Fissure: A controlled Clinical Trial

Protocol summary

Study aim
To determine the effect of oral probiotics on symptoms in patients with acute anal fissure refractory to standard treatment.

Design
A phase II, randomized, controlled, parallel-group, double-blind clinical trial will be conducted in 60 patients. Randomization will be performed using the Sealed Envelope online randomization service (https://www.sealedenvelope.com).

Settings and conduct
This study will be conducted in Yasuj, Iran. Patients with acute anal fissure confirmed by a specialist physician will be enrolled in the study. Participants will be followed for two weeks before and two weeks after the intervention. The intervention group will receive an oral probiotic capsule (Bio IBS), administered twice daily for 8 weeks, in addition to standard treatment. The control group will receive standard treatment + Placebo. The study will employ a double-blind design, with both the patients and the outcome assessor (surgeon) blinded to group allocation.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: * Patients aged ≥18 years with acute anal fissure confirmed by a specialist physician **Exclusion Criterion:** * Concomitant use of medications that may affect wound healing or immunosuppressive medications.

Intervention groups
Intervention: Participants in the intervention group will receive an oral probiotic capsule (Bio IBS), with each capsule containing three probiotic strains: *Lactobacillus casei*, *Lactobacillus rhamnosus*, and *Lactobacillus acidophilus*, providing a total of 5×10^9 colony-forming units (CFUs) per capsule. The probiotic will be administered twice daily for 8 weeks in addition to standard treatment **Control:** Participants in the control group will receive standard treatment alone, consisting of warm sitz baths, topical diltiazem anti-fissure ointment, and lactulose + Placebo

Main outcome variables
Pain; pruritus; bleeding

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260815070659N1**
Registration date: **2026-10-17, 1405/07/25**
Registration timing: **prospective**

Last update: **2026-10-17, 1405/07/25**
Update count: **0**

Registration date
2026-10-17, 1405/07/25

Registrant information

Name
Hamid-Reza Ahmadi Amin Ahmadi Amin

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-10-22, 1405/07/30

Expected recruitment end date
2027-01-20, 1405/10/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Oral Probiotics on Symptoms in Patients with Treatment-Resistant Acute Anal Fissure: A controlled Clinical Trial

Public title

Effect of Oral Probiotics on Symptoms of Acute Treatment-Resistant Anal Fissure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 years of age with physician-confirmed acute anal fissure Less than 6 weeks since symptom onset History of resistance to standard first-line treatment for 2 weeks

Exclusion criteria:

History of hypersensitivity or allergy to probiotic components

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated to the intervention and control groups using variable block randomization with block sizes of 2, 4, 6, and 8 and an allocation ratio of 1:1. The individual participant will be the unit of randomization. The random allocation sequence will be generated before participant recruitment using the online Sealed Envelope tool. The allocation sequence will be generated and maintained by an individual independent of participant recruitment and assessment. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes. After eligibility has been confirmed, informed consent has been obtained, and baseline assessments have been completed, the corresponding envelope will be opened in numerical order to reveal the participant's group allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be conducted using a double-blind design. The outcome assessor (surgeon) and data analyst will be blinded to group allocation and will be unaware of whether participants are assigned to the intervention or control group. The probiotic and placebo capsules will be identical in appearance, color, odor, and packaging. Participants will also be blinded to the intervention they receive.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Daneshgah St., Motahari Blvd., Jahad Town

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591875111

Approval date

2026-07-15, 1405/04/24

Ethics committee reference number

IR.YUMS.REC.1405.085

Health conditions studied

1

Description of health condition studied

Acute anal fissure

ICD-10 code

K60.0

ICD-10 code description

Acute anal fissure

Primary outcomes

1

Description

Pain

Timepoint

2 weeks before the start of the intervention – 2 weeks after the end of the intervention

Method of measurement

visual analogue Scale (VAS)

2

Description

Pruritus ani

Timepoint
2 weeks before the start of the intervention – 2 weeks after the end of the intervention
Method of measurement
visual analogue Scale (VAS)

3

Description
Bleeding
Timepoint
2 weeks before the start of the intervention – 2 weeks after the end of the intervention
Method of measurement
Using a 4-point Likert scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Participants in the intervention group will receive an oral probiotic capsule (Bio IBS) (Takgene Zist Company), with each capsule containing three probiotic strains: *Lactobacillus casei*, *Lactobacillus rhamnosus*, and *Lactobacillus acidophilus*, providing a total of 5×10^9 colony-forming units (CFU) per capsule. The probiotic will be administered twice daily for 8 weeks, in addition to standard treatment, including warm sitz baths, topical diltiazem (Anti-Fissure) ointment, and lactulose.
Category
Treatment - Other

2

Description
Control group: Standard treatment, consisting of warm sitz baths, topical diltiazem (Anti-Fissure) ointment, and lactulose, will be administered for 8 weeks + Placebo
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mofateh Clinic
Full name of responsible person
Amin Mareshi
Street address
Golestan12 St., Artesh Blvd., Golestan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
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Phone
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Email
research@yums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Seyed Majid Ahmadi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Shahid Zarei Educational Campus, Beach Park

Towards Imam Sajjad (AS) Hospital, Yasuj

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Person responsible for updating data

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Position
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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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
After the completion of the study, all study data will be shared after being de-identified

When the data will become available and for how long
One month after the completion of the intervention, the data of the main variables of the study will be shared.

To whom data/document is available
The study data will be available to academic and scientific researchers working at medical science centers.

Under which criteria data/document could be used
Individuals associated with the medical and therapeutic fields may utilize the data from this study to conduct new research.

From where data/document is obtainable
Via official email to the corresponding author at: majidahmadi1385@yahoo.com

What processes are involved for a request to access data/document
The applicant must submit their formal request via the organization's email to the responsible author's email address. The accountable author will provide the information to the applicant within a maximum of 2 weeks after the applicant confirms the information.

Comments