Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Encapsulation of Lactobacillus rhamnosus probiotic bacteria by electrospinning method using ploy di actelene polymer.

Protocol summary

Study aim
Investigating the effect of Lactobacillus rhamnosus probiotic on constipation.

Design
Randomized clinical trial with control group-placebo and double-blind with two parallel groups. Study phase: 3 block randomization. Expected sample size: 50 people, 25 people in the intervention group and 25 people in the control group.

Settings and conduct
The samples will be selected from among those who visit the gastroenterology clinic of Hazrat Masoumeh (former Khorrami) and Shahid Beheshti hospitals in Qom. Product packaging will be coded by the company in two ways. The codes are kept secret by the company from the patients and researchers and will be announced to the researchers after the completion of the clinical trial by the company.

Participants/Inclusion and exclusion criteria
Entry conditions: people who are 18 years old and above, people who are diagnosed with moderate and mild constipation based on the Rome criteria, people who consent to participate in the study. Exit conditions: lack of mobility and drug addiction activity. A known metabolic disorder (diabetes) Taking a special drug that interferes with these drugs Taking a drug to treat neurological and mental disorders Not taking the drug according to the schedule (if the drug is not taken 4 times a week) Receiving treatment for constipation in the previous 2 weeks from entering the study, symptoms of acute gastroenteritis such as: nausea, vomiting and diarrhea during the study.

Intervention groups
Intervention group: Patients will consume Familact® probiotic capsules. Control group: patients will take placebo capsules.

Main outcome variables
1. Severity of abdominal pain 2. The degree of discomfort or heaviness in the abdomen 3. The degree of bloating or abdominal swelling 4. Heartburn

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230105057061N1**
Registration date: **2023-08-22, 1402/05/31**
Registration timing: **retrospective**

Last update: **2023-08-22, 1402/05/31**
Update count: **0**

Registration date
2023-08-22, 1402/05/31

Registrant information

Name
Esmaeel Qashamzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 25 3288 6211

Email address
qashamzadeh1399@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-02, 1402/02/12

Expected recruitment end date
2023-06-02, 1402/03/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Encapsulation of Lactobacillus rhamnosus probiotic bacteria by electrospinning method using ploy di actelene polymer.

Public title
Encapsulation of Lactobacillus rhamnosus bacteria

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The main conditions for entering the study before randomization: patients will be selected based on the Rome II criteria according to the diagnosis of digestive and liver diseases; (Rome II criteria: abdominal pain or any digestive discomfort for at least 3 months during a year) The past three months can be consecutive or non-consecutive, along with two of the following three: resolution of pain with defecation, onset of symptoms with change in frequency of defecation, onset of symptoms with change in stool shape) minimum age 18 years of informed consent of the patient, which is adopted in writing after providing all the necessary explanations for them.

Exclusion criteria:
The main conditions of non-entry into the study before randomization: a history of major gastrointestinal surgery, chronic use of antibiotics, corticosteroids, and immunosuppressive drugs, regular use of drugs that change the movements of the digestive system, such as metoclopramide, cisapride, domperidone, narcotics, especially Opioid derivatives, laxative agents, antidiarrheal agents, and other drugs effective in the treatment of IBS, which are described in more detail in the text. The presence of severe mental and behavioral disorders in the patient, the presence of food allergies, the presence of any organic intestinal disease or chronic digestive disease

Age
From **9 years** old to **80 years** old

Gender
Male

Phase
0

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
Randomized

Randomization description
In this clinical trial study, the sample size is estimated to be 50 people, and finally 25 people will be in the intervention group and 25 people will be in the control group. The samples will be selected from among those who visit the gastroenterology clinic of Khorrami (Hazrat Masoumeh) and Shahid Beheshti Hospitals in Qom. Product packaging will be coded by the company in two ways. Each of the two randomly divided groups will receive a type of drug code. The codes are kept secret by the company from the patients and researchers and will be announced to the researchers at the end of the study after the completion of the clinical trial by the company.

Blinding (investigator's opinion)
Double blinded

Blinding description
The upcoming clinical trial will be conducted in a randomized, double-blind, placebo-control group. In this clinical trial study, the sample size is estimated to be 50 people, and finally 25 people will be in the intervention group and 25 people will be in the control group. Blocked randomization method is considered for this study. In this way, the first qualified patient enters group A and the second one enters group B, and in the same way, the rest of the patients are divided between the two groups one after the other.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Islamic Azad University Qom branch

Street address
Islamic Azad University, Qom branch, 15 Khordad Blvd.

City
Qom

Province
Ghoum

Postal code
3714963744

Approval date
2023-04-11, 1402/01/22

Ethics committee reference number
IR.IAU.Qom.REC.1402.021

Health conditions studied

1

Description of health condition studied
Constipation and gastrointestinal cancer

ICD-10 code
C26.9

ICD-10 code description
Gastrointestinal tract NOS

Primary outcomes

1

Description
Abdominal pain intensity
Timepoint
At the beginning of the study (before the start of the intervention) and at the end of the study (the end of the intervention) during the intervention and 3 months after the intervention
Method of measurement
Questionnaire (numbers 0 to 10 to check pain intensity, where 0 represents the absence of pain and 10 represents very intense pain)

2

Description
Timepoint
Method of measurement

Secondary outcomes

1

Description
Albumin and pre-albumin
Timepoint
Before the intervention, during the intervention and 3 months after the intervention
Method of measurement
Laboratory kits

2

Description
Alkaline phosphatase
Timepoint
Before the intervention, during the intervention and 3 months after the intervention
Method of measurement
Laboratory kits

3

Description
Alanine aminotransferase
Timepoint
Before the intervention, during the intervention and 3 months after the intervention
Method of measurement
Laboratory kits

4

Description
Erythrocyte sedimentation rate (ESR)
Timepoint
Before the intervention, during the intervention and 3 months after the intervention
Method of measurement
Laboratory kits

Intervention groups

1

Description
Control group: patients for 30 consecutive days, daily two 500 mg capsules of placebo containing an ineffective substance with the same shape and appearance and packaging as the original drug and unrecognizable to patients and researchers by the company (Danish Biopharmaceutical Company, (Tehran) designed and produced will consume. Since it is indistinguishable from the original drug, it is recommended to take it at the same time as the original drug, between each meal.
Category
Placebo

2

Description
Control group: use of dietary supplements Figilax and Fitolax as well as folic acid and zinc in a period of 90 days
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital, Qom
Full name of responsible person
Dr. Seyed Saeed Sarkashikian
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Shahid Beheshti Hospital, Shahid Beheshti Street,Qom ,iran
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3719964797
Phone
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Email
qashamzadeh1399@gmail.com

2

Recruitment center
Name of recruitment center
Hazrat Masoumeh Hospital, Qom
Full name of responsible person
Gholam Ali Jafari
Street address
H.hospital,Imam Khomeini Street, after Shahid Zain al-Din Square, next to Imam Hassan Mosque,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mahbouba Al Sadat Sharif
Street address
15 Khordad Blve, Islamic Azad University, Qom branch
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3749113191
Phone
+98 25 3280 8080
Email
info@qom-iau.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University
Proportion provided by this source
100
Public or private sector
Private
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
Islamic Azad University
Full name of responsible person
Islamic Azad University
Position
Member of the academic staff of Islamic Azad University, Qom branch
Latest degree
Ph.D.
Other areas of specialty/work
Nuclear Medicine
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Person responsible for updating data

Contact
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Student
Latest degree
Bachelor
Other areas of specialty/work
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qashamzadeh1399@gmail.com

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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
SPSS file data by de-identifying individual characteristics after The completion and printing of this study will be available to the applicant researchers took
When the data will become available and for how long
The access period starts after the results are printed
To whom data/document is available
Both researchers and related industries
Under which criteria data/document could be used
Any kind of scientific, practical and research use with awareness and acquisition Consent from researchers is allowed.
From where data/document is obtainable
Refer to the researchers of the project, e-mail: qashamzadeh1399@gmail.com
What processes are involved for a request to access data/document
While sending the request by email, complete identification information including name and Surname and membership number in a scientific, research or industrial authority and Provide a full explanation of the type of data use and its purposes to do
Comments