Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Feasibility Study of Fecal Microbiota Transplantation (FMT) in Patients with Ulcerative Colitis

Protocol summary

Study aim
The assessment and comparison of clinical feature score and the stool targeted microbiome count due to fecal microbiota transplantation in patients with ulcerative colitis

Design
In a feasibility study of phase 1-2 clinical trial, 5 patients with ulcerative colitis and 5 healthy stool donors based on inclusion and exclusion criteria in non-probable method were enrolled.

Settings and conduct
The reception and preparation of the fresh stool for injection from healthy donors will be done based on the standard protocols. The solution will be injected to patients' large intestine via colonoscopy every 2 weeks for 2 months in gastrointestinal health center, Isfahan university of medical sciences. The clinical feature for the patients will be assessed at the beginning, after 2 months and after 4 months by LIGHTIGER score test. In addition, the count of targeted gut microbiota using quantitate-real time-PCR will be evaluated before the study and after 4 months for the patients and before the study for healthy donors.

Participants/Inclusion and exclusion criteria
For the patients: patients 18-65 years with at list 3 months diagnosis of ulcerative colitis For the stool donors: The healthy volunteer 18-65 years subjects without any condition or sign of gastrointestinal diseases or infections, diabetes, cardiovascular diseases, and also hepatic, kidney, and psychological disease, not use of anti biotic, anti fungal, anti viral, or probiotics during past 3 months

Intervention groups
300 cc refined stool obtained from 50 gr stool of healthy donor will be injected to the colon of 5 patients with ulcerative colitis by colonoscopy each 2 weeks for 2 months. There is not any control group.

Main outcome variables
Clinical symptom score; quantity of targeted Gut microbiota

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210113050024N1**
Registration date: **2021-02-08, 1399/11/20**
Registration timing: **prospective**

Last update: **2021-02-08, 1399/11/20**
Update count: **0**

Registration date
2021-02-08, 1399/11/20

Registrant information

Name
Nazila Kassaian

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3237 4705

Email address
nkassaian@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-08, 1400/01/19

Expected recruitment end date
2021-08-05, 1400/05/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Feasibility Study of Fecal Microbiota Transplantation (FMT) in Patients with Ulcerative Colitis

Public title
Fecal Microbiota Transplantation in Patients with Ulcerative Colitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
For the patients: the volunteers aged 18-65 years with Ulcerative Colitis who have been diagnosed by 3 months and are in moderate-severe phase For the stool donor: the healthy volunteers aged 18-65 years
Exclusion criteria:
For the stool donor: Having signs or existence of gastro-enteric diseases existence of other diseases like diabetes, cardiovascular, liver, and kidney diseases Using antibiotic/ anti fungal/ anti viral or probiotics Using immunosuppressive and anti carcinogenic drugs affected by autoimmune and atopic diseases With metabolic syndrome, obesity(BMI>30) or under nutrition(BMI<18) chronic pain syndrome, psychological diseases, and carcinoma Infectious disease like hepatitis B, hepatitis C, AIDS, and respiratory infections Close contact to somebody who have had viral hepatitis or AIDS during the last year high risk behaviors like sigh risky sex, tattooing, or piercing in the last 6 months consumption illegal drugs and opium going to diarrheic endemic zone during the last 6 months the history of inflammation bowel diseases, chronic diarrhea and the other GI diseases the history of GI cancer or Polyposis the history of colorectal cancer in the first degree relatives the history of GI surgery like bypass infected by corona virus
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **5**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
This is phase 2 clinical trial which has one group receiving intervention

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The ethical committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Research Chancelor, Hezarjerib st., Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
81745319
Approval date
2021-01-06, 1399/10/17
Ethics committee reference number
IR.MUI.MED.REC.1399.899

Health conditions studied

1

Description of health condition studied
Ulcerative colitis
ICD-10 code
K51
ICD-10 code description
Ulcerative colitis

Primary outcomes

1

Description
the clinical score based on Lightiger test
Timepoint
at the first(mo 0), after intervention period(mo 2), at the end(mo 4)
Method of measurement
using Lightiger questionnaire

2

Description
quantity of intestinal targeted bacteria
Timepoint
at the first(mo 0), and at the end(mo 4) of study
Method of measurement
Q-PCR

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 5 patients with ulcerative colitis and 5 healthy donors according to inclusion and exclusion criteria using non-probable method will enter into the study. The fresh stool samples were obtained from the healthy donors following the standard protocol. 300cc diluted-filtered stool extracted from 50gr solid stool from healthy donors will be injected into the patients' large intestine through colonoscopy, every 2 weeks during 2 months. There is no control group.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
gastroenterology and hepatology research center, Isfahan University of Medical Sciences, Isfahan, I

Full name of responsible person
Nazila Kassaian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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research@mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Nazila Kassaian

Position
Researcher

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Babak Tamizifar

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Person responsible for updating data

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Title and more details about the data/document

The informed consent will be available The data set will be available The statistical data analysis will be available

When the data will become available and for how long

The informed consent will be shared at the end of the study The data set will be shared after publication The statistical data analysis will be shared after publication

To whom data/document is available

The data will be available for the researchers in scientific and educational centers around the world

Under which criteria data/document could be used

Use of the data for second analysis will be possible in condition of execute satisfaction

From where data/document is obtainable

Dr. Nazila Kassaian , Dr. Babak Tamizifar Gastrointestinal and hepatology Research Center, Isfahan University of Medical Sciences, Isfahan, Iran 009831-38222675 ighrc@mui.ac.ir

What processes are involved for a request to access data/document

It is sufficient to contact with the executes for data request. The data will be submitted during one week in condition of agreement.

Comments