

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of improvement quality of life before and after lactulose and probiotic in cirrhotic patient

Protocol summary

Study aim

The aim of this study was to evaluate the effects of lactulose and probiotics on the quality of life in cirrhotic patients.

Design

The present study is a clinical trial of phase 3, randomized, double-blind, and parallel, which will be performed on 80 patients with cirrhosis. Patients are randomly divided into two groups.

Settings and conduct

The Quality of Life Questionnaire for Chronic Hepatic Patients (CLDQ), which is based on the patient's symptoms and feelings from 1 to 7, as well as demographic information, will be obtained from the patients. this study will be conducted in the gastroenterology clinic, imam hospital, Ahvaz. Patients are randomized to receive lactulose alone and probiotic lactulose in a group of 40.

Participants/Inclusion and exclusion criteria

patients with cirrhosis for any reason, age above 18.
exclusion criteria: History of other chronic diseases other than cirrhosis, History of chronic psychosomatic illness, moderate to severe encephalopathy, brain damage, active infection, active bleeding, acute renal failure, continuous use of occipital benzodiazepines, patient dissatisfaction and probiotic contraindications, such as the use of suppressive drugs or acute and severe infections.

Intervention groups

Patients with cirrhosis are randomly divided into two groups of 40 lactulose alone and probiotic plus lactulose.

Main outcome variables

Quality of life in patients with cirrhosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190306042944N1**

Registration date: **2019-04-14, 1398/01/25**

Registration timing: **registered_while_recruiting**

Last update: **2019-04-14, 1398/01/25**

Update count: **0**

Registration date

2019-04-14, 1398/01/25

Registrant information

Name

Damoon Dehnavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 3542

Email address

dr.damoon@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of improvement quality of life before and after lactulose and probiotic in cirrhotic patient

Public title

effect of probiotic in cirrhosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

cirrhosis with any reasons Age above 18

Exclusion criteria:

Chronic physical or sychiatric illness Encephalopathy

Active infection Addiction Intake immunosuppressive drugs Patient Dissatisfaction

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in this study will be done by a simple method. The unit of randomization is the individual.

Using a random number table, a number is considered for each patient, respectively.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, only the patient should be kept blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Science

Street address

Research Deputy of Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6135815751

Approval date

2019-02-23, 1397/12/04

Ethics committee reference number

IR.AJUMS.REC.1397.881

Health conditions studied

1

Description of health condition studied

Cirrhosis

ICD-10 code

K74

ICD-10 code description

Fibrosis and cirrhosis of liver

Primary outcomes

1

Description

quality of life in cirrhosis patients

Timepoint

At the beginning of the study and 3 months later (end of the study)

Method of measurement

According to the quality of life questionnaire for chronic liver patients (CLDQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Lactulose plus probiotics

Category

Treatment - Drugs

2

Description

Intervention group: Lactulose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology clinic of Ahvaz Imam Khomeini Hospital

Full name of responsible person

Eskandar Hajiani

Street address

Azadegan Blvd. Imam khomeini hospital

City

Ahvaz

Province

Khouzestan

Postal code
6135815751
Phone
+98 61 3221 6104
Fax
+98 61 3221 6104
Email
dr.damoon@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad badavi
Street address
Golestan Blvd., Jundishapur University of Medical Sciences, Ahvaz, Deputy of Research and Technology Development
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3336 7570
Fax
+98 61 3336 1544
Email
badavi-m@ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Damoon Dehnavi
Position
Student of specialty

Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Azadegan Ave. Imam khomeini Hospiatl
City
Ahvaz
Province
Khouzestan
Postal code
6135815751
Phone
+98 61 3321 4578
Email
dr.damoon@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Damoon Dehnavi
Position
Student of specialty
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Azadegan Blvd. Imam Khomeini hospital
City
Ahvaz
Province
Khouzestan
Postal code
6135815751
Phone
+98 61 3321 4578
Email
dr.damoon@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Damoon Dehnavi
Position
Student of specialty
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Azadegan Ave. Imam khomeini Hospiatl
City
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Email

dr.damoon@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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

If the decision is to publicate the data, after the unidentified individuals all data will be publicated.

When the data will become available and for how long

The access period will be 6 months after the publication of the results.

To whom data/document is available

Researchers working in academic and industrial institutions can apply to get data.

Under which criteria data/document could be used

To cite. Referring to reference or researcher's permission

From where data/document is obtainable

Dr. Damoon Dehnavi dr.damoon@yahoo.com

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

Access to articles related to this research Send an email to the responsible author

Comments