

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Effect of probiotic (Lactobacillus sporogenesis) in reducing PELD score in pediatric cholestatic liver disease: Randomized double blinded clinical trial

Protocol summary

Study aim

Effect of probiotic (Lactobacillus sporogenesis) in reducing PELD score in pediatric cholestatic liver disease: Randomized double blinded clinical trial

Design

The convince sampling method is goal-based. In this way, the researcher is present at the site during the study and starts sampling from the referring patients in an accessible way to get the total sample size. Randomization method: permutation block design or quadruple blocks will be used

Settings and conduct

Children with cirrhosis who refer to Shiraz pediatric liver Cirrhosis Cohort Center located in Motahhari clinic

Participants/Inclusion and exclusion criteria

Cirrhotic children who refereed to Motaharei clinic in Shiraz. inclusion criteria: age 1-12 years. cholestatic liver disease. signed informed consent Exclusion criteria: Taking antibiotics for four weeks before the study, history of gastrointestinal bleeding or SBP over the past two months, active microbial infection, taking immunosuppressive drugs or Immunosuppressed patients , renal failure (more creatinine From 1.5 mg) electronic imbalance (serum sodium <130 or> 150 meq / dl, serum potassium <3.0 or> 5.5 meq / dl), people with a history of allergies

Intervention groups

Lactobacillus sporogenesis probiotic is given in drops for 1 month (5 drops per day in 2 intervals) to treatment group.

Main outcome variables

PELD score: age, total Bili, Alb, INR, History of growth failure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200628047940N1**
Registration date: **2020-07-21, 1399/04/31**
Registration timing: **prospective**

Last update: **2020-07-21, 1399/04/31**

Update count: **0**

Registration date

2020-07-21, 1399/04/31

Registrant information

Name

Nasrin Motazedian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 1529

Email address

nmotazedi@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-05, 1399/05/15

Expected recruitment end date

2021-01-04, 1399/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of probiotic (Lactobacillus sporogenesis) in

reducing PELD score in pediatric cholestatic liver disease:Randomized double blinded clinical trial

Public title

Effect of probiotic in pediatric cholestatic liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age1-12 cholestatic liver failure informed consent

Exclusion criteria:

Taking antibiotics for four weeks before the study Active microbial infection History of gastrointestinal bleeding over the past two months History of SBP over the past two months Taking immunosuppressive drugs Immunosuppressed patients Renal failure (creatinine> 1.5 mg) Electronic imbalance (serum sodium <130 or> 150 meq / dl, serum potassium <3.0 or> 5.5 meq / dl) History of Allergies

Age

From **1 year** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The convince sampling method is goal-based. In this way, the researcher is present at the site during the study and starts sampling from the referring patients in an accessible way to get the total sample size. Randomization method: permutation block design or quadruple blocks will be used

Blinding (investigator's opinion)

Double blinded

Blinding description

The physician will examine the patient and evaluate the laboratory tests under blinded conditions.The case and control groups are also unaware of the nature of the drops (probiotic, and placebo).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Ethics Committee, Shiraz University of Medical Sciences, Zand Street, Beside Helal Ahmar, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2020-06-02, 1399/03/13

Ethics committee reference number

IR.SUMS.REC.1399.277

Health conditions studied

1

Description of health condition studied

Cholestatic liver disease in children

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Change in Pediatric End-Stage Liver Disease (PELD) score

Timepoint

The results of Lab test for calculation of Pediatric End-Stage Liver Disease (PELD) score will be evaluated one month, three months after finishing the intervention.

Method of measurement

Pediatric End-Stage Liver Disease (PELD) Score = $0.480 \times \text{Loge}(\text{bilirubin mg/dL}) + 1.857 \times \text{Loge}(\text{INR}) - 0.687 \times \text{Loge}(\text{albumin g/dL}) + 0.436$ (if the patient is less than 1 year old) + 0.667 if the patient has growth failure (< -2 Standard deviation). Then multiply the score by 10 and round to the nearest whole number.

Secondary outcomes

1

Description

Improvement in growth and development

Timepoint

Three months after finishing the study

Method of measurement

Measuring weight by scale and height by stadiometer

Intervention groups

1

Description

Intervention group: The treatment group will be received Lactobacillus sporogenesis probiotic is given in drops for 1 month (5 drops per day in two intervals)

Category

Treatment - Drugs

2

Description

Control group: placebo drops is given in drops for 1 month (5 drops per day in two intervals) to control group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Transplant Research Center

Full name of responsible person

Nasrin Motazedian

Street address

Seventh floor, Transplant Research Center, Research Tower, Mollasadra St., Khalili Ave., Shiraz, IR Iran.

City

Shiraz

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Postal code

7193711351

Phone

+98 71 3628 1529

Email

motazediann@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Nasrin Motazedian

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Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Proportion provided by this source

60

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

Shiraz University of Medical Sciences

Full name of responsible person

Nasrin Motazedian

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The patients selected by convince sampling

Study Protocol

No - There is not 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

gender age underlying disease drugs INR AST ALT growth and development chart

When the data will become available and for how long

1400

To whom data/document is available

Pediatrics transplant surgeon /Pediatrics gastroenterologist

Under which criteria data/document could be used

Privacy and Ownership of the principal investigator

From where data/document is obtainable

Seventh floor, Transplant Research Center, Research Tower, Mollasadra St., Khalili Ave., Shiraz, IR Iran.

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

Request by e- mail and present to sign agreement

Comments