Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

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

Protocol summary

Study aim

Effect of probiotic (Lactobacilus 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

Lactobacilus 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 (Lactobacilus 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 Commitee, 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 × Loge (bilirubin mg/dL) + 1.857 × Loge (INR) - 0.687 × Loge (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 Lactobacilus 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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7193711351
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motazediann@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Nasrin Motazedian
Street address
Seventh floor, Transplant Research Center, Research Tower, Mollasadra St., Khalili Ave., Shiraz, IR Iran.
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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 ofMedical 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
Street address
Seventh floor, Transplant Research Center, Research Tower, Mollasadra St., Khalili Ave., Shiraz, IR Iran.
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Person responsible for scientific inquiries

Contact
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Shiraz University of Medical Sciences
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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