

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Effect of Curcumin supplement on disease activity in patients with liver cirrhosis

Protocol summary

Study aim

The aim of this study is evaluation of the effect of curcumin supplement on disease activity in patients with liver cirrhosis.

Design

70 person after taking informed consent consist of 35 patient with liver cirrhosis in case group and 35 patient with the liver cirrhosis in control group conducted parallel double blinded in the trial.

Settings and conduct

The trial will be performed in Tabriz Emam Reza hospital in the special liver cirrhosis clinic by managing study and control groups. Curcumin supplement(500mg) and placebo will be administered twice a day for 90days, while patients and physician are blind in the study. Lab tests will be obtained and documented when referring patients to the clinic on schedules and at the end, by using the computer software the data will be analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18-65 MELD score < 18 PaO₂ u> 60mmHg Without hepatocellular carcinoma and hepatopulmonary syndrome and pulmonary hypertension and without consumption of anti platelet and anti coagulant without Cholelithiasis and Bladder stone Exclusion criteria: Exceeding of MELD score > 18 PaO₂ <60 mmHg Hepatopulmonary syndrome Pulmonary artery pressure > 25 mmHg Hyper oxaluria Hillar chlangio carcinoma Cystic fibrosis with FEV1< 40%

Intervention groups

In case group 1000mg of Curcumin supplement divided in 2 doses daily for the months will be described and the control group will take placebo

Main outcome variables

MELD(i) Score, MELD Score, Child-Paugh Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180802040678N1**

Registration date: **2018-12-31, 1397/10/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-31, 1397/10/10**

Update count: **0**

Registration date

2018-12-31, 1397/10/10

Registrant information

Name

Masoud Nouri-Vaskeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3325 9778

Email address

mnvaskeh@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-19, 1397/09/28

Expected recruitment end date

2019-06-20, 1398/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Curcumin supplement on disease activity in patients with liver cirrhosis

Public title

Effect of Curcumin supplement on disease activity in patients with liver cirrhosis

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 MELD Score below 18 PaO2 upper than 60 mmHg without Hepato Cellular Carcinoma Without Hepato pulmonary syndrome Without consumption of antiplatelet and anti coagulant drugs Without Cholelithiasis and Bladder stone
Exclusion criteria:
 MELD Score above 18 PaO2 less than 60 mmHg Hepato pulmonary syndrome Pulmonary artery pressure above 25mmHg Hyper Oxaluria Hillar cholangio carcinoma Cystic fibrosis with FEV1 less than 40%

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomizing by computer software

Blinding (investigator's opinion)
Double blinded

Blinding description
participants-healthcare provider-data collectors

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Tabriz University of Medical Sciences
Street address
 Tabriz University of Medical Sciences, Golgasht Ave.
City
 Tabriz
Province
 East Azarbaijan

Postal code
516615731
Approval date
2018-11-19, 1397/08/28
Ethics committee reference number
 IR.TBZMED.REC.1397.660

Health conditions studied

1

Description of health condition studied
 Liver Cirrhosis
ICD-10 code
 K74
ICD-10 code description
 Fibrosis and cirrhosis of liver

Primary outcomes

1

Description
 MELD (i) Score
Timepoint
 Every two week
Method of measurement

$$\text{MELD (i) Score} = 10 * ((0.957 * \ln(\text{Creatinine})) + (0.378 * \ln(\text{Bilirubin})) + (1.12 * \ln(\text{INR})) + 6.43$$

2

Description
 Child-Pugh Score
Timepoint
 Every two week
Method of measurement
 According to formula: Total Bilirubin, INR, Albumin, Ascites, Encephalopathy (Laboratory, Imaging and clinical methods)

3

Description
 MELD Score
Timepoint
 Every Two Week
Method of measurement

$$\text{MELD} = \text{MELD}(i) + 1.32 \times (137 - \text{Na}) - [0.033 \times \text{MELD}(i) \times (137 - \text{Na})]$$

Secondary outcomes

1

Description
 Aspartate Aminotransferase (AST)
Timepoint
 Once a month
Method of measurement
 Laboratory Assay

2

Description

Alanine Aminotransferase (ALT)

Timepoint

Once a month

Method of measurement

Laboratory Assay

3

Description

Alkaline Phosphatase

Timepoint

Once a month

Method of measurement

Laboratory Assay

4

Description

Prothrombin Time (PT)

Timepoint

Once a month

Method of measurement

Laboratory Method

5

Description

Partial Thromboplastin Time (PTT)

Timepoint

Once a month

Method of measurement

Laboratory Assay

Intervention groups

1

Description

Intervention group: Administration of Curcumin 500mg supplement twice a day for 90 days

Category

Treatment - Drugs

2

Description

Control group: Administration of placebo

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital of Tabriz University of Medical Sciences

Full name of responsible person

Hossein Afshan

Street address

Imam Reza Hospital, Golgasht Ave.

City

Tabriz

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East Azarbaijan

Postal code

516615731

Phone

+98 41 3335 7314

Email

mnvaskeh@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Abolghasem Jouyban

Street address

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medfa@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Masoud Nouri-Vaskeh

Position

M.D.

Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Tabriz University of Medical Sciences, Golgasht Ave.
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Leila Alizadeh
Position
Assistant Professor
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Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Aida Malek Mahdavi
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Assistant Professor
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Other areas of specialty/work
Nutrition
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aidamalek@gmail.com

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
Abuse is possible
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
Not applicable
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
Information about the study is available upon approval by the University's Ethics Committee.
When the data will become available and for how long
Starting access 6 months after publication of data
To whom data/document is available
everybody
Under which criteria data/document could be used
Using is not authorized
From where data/document is obtainable
Applicants must send their request to the author
What processes are involved for a request to access data/document
Sending the request via e-mail
Comments