Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 administerated 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 Choleliyhiasis 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

MELD (i) Score= 10 * ((0.957 * ln(Creatinine)) + (0.378 * ln(Bilirubin)) + (1.12 * ln(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

MELD = MELD(i) + 1.32 × (137 – Na) – [0.033 × MELD(i) × (137 – 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
Province
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
University of medical sciences,Golgasht Ave
City
Tabriz
Province
East Azarbaijan
Postal code
516615731
Phone
+98 41 3335 7314
Email
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
Street address
Tabriz University of Medical Scinces, Golgasht Ave.
City
Tabriz
Province
East Azarbaijan
Postal code
516615731
Phone
+98 911 184 4299
Email
mnvaskeh@tbzmed.ac.ir

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
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Golgasht Ave.
City
Tabriz
Province
West Azarbaijan
Postal code
516615731
Phone
+98 41 3335 4844
Email
alizadele@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Aida Malek Mahdavi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Golgasht Ave.
City
Tabriz
Province
West Azarbaijan
Postal code
516615731
Phone
+98 41 3336 9331
Email
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