

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of a diet based on the principles of traditional medicine on the clinical symptoms and Para clinical in the Class A and B patients with cirrhosis admitted to Imam Hussein and Taleghani hospital in 92-93 years

Protocol summary

Summary

Aims: the goal of the project was to determine the effect of a diet based on the principles of Iranian Traditional Medicine Clinical and Para clinical patients with liver cirrhosis classes A and B referred to Imam Hussein and Taleghani hospital in 92-93 years. Design: this studies a randomized controlled clinical trial, Phase 2 clinical trial. Setting and conduct: they are divided into two groups: the experimental group and the control group. The experimental group received diet plan and the control group received instructions to maintain health based on the principles of Traditional Medicine. Number of cases is 80 and during the 3-month study. Including criteria: Class A and B cirrhotic patients diagnosed with ultrasound in age from 20-70 years and in the past two weeks have not been ill and acute complications and diabetes, Hepato cellular carcinoma, hepatic encephalopathy, and chronic renal failure are not included. Excluding criteria: Failure to follow instructions for two weeks and Complications that lead to hospitalization and Intolerance Diet Plan whatever reason exclusion is due. The main outcome variables: tests: albumin, bilirubin, INR, serum creatinine and LFT before and after the designs are evaluated, nausea and vomiting, muscle spasms are assessed with questionnaires and malnutrition with BMI.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013122415864N1**

Registration date: **2014-02-06, 1392/11/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-02-06, 1392/11/17

Registrant information

Name

Jamileh Mahdavi Jafari

Name of organization / entity

School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center, Shahid Beheshti

Country

Iran (Islamic Republic of)

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+98 21 8877 3522

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jmahdavi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of a diet based on the principles of traditional medicine on the clinical symptoms and Para clinical in the Class A and B patients with cirrhosis admitted to Imam Hussein and Taleghani hospital in 92-93 years

Public title

Effect of diet based on the principles of traditional medicine in cirrhosis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Class A and B cirrhosis diagnosed by ultrasonography; Age 20-70; Informed consent; Lack of complications of acute illness within 2 weeks; Not get out of the routine treatment protocols over the past 2 weeks; Non- hepato cellular carcinoma; Lack of hepatic encephalopathy; Lack of chronic renal failure; Non-diabetic. Exclusion criteria were: Failure to follow instructions for two weeks; Complications leading to hospitalization; Intolerance Diet Plan whatever reason.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences, Office of Research Affairs, Depu

Street address

Parvaneh St., Yemen St., Shahid Chamran Highway, next to Taleghani Hospital, Sixth Floor, College Staff Building Number Two, Shahid Beheshti University of Medical Sciences

City

Tehran

Postal code

Approval date

2013-12-29, 1392/10/08

Ethics committee reference number

144

Health conditions studied

1

Description of health condition studied

cirrhosis of liver

ICD-10 code

K74.6

ICD-10 code description

Other and unspecified cirrhosis of liver

Primary outcomes

1

Description

Body Mass Index

Timepoint

Before intervention & week 12 after intervention

Method of measurement

Balance & Meter

2

Description

Muscle spasm

Timepoint

Weeks 4, 8 &12 from start of intervention

Method of measurement

Question from patient

3

Description

Nausea and vomiting

Timepoint

Weeks 4, 8 &12 from start of intervention

Method of measurement

Question from patient

4

Description

Serum Albumin

Timepoint

Before intervention & week 12 after intervention

Method of measurement

Electrophoresis

5

Description

Bilirubin Total

Timepoint

Before intervention & week 12 after intervention

Method of measurement

Spectrophotometer

6

Description

International normalized ratio

Timepoint

Before intervention & week 12 after intervention
Method of measurement
Spectrophotometer

7

Description
Aspartate aminotransferase
Timepoint
Before intervention & week 12 after intervention
Method of measurement
Spectrophotometer

8

Description
Alanine transaminase
Timepoint
Before intervention & week 12 after intervention
Method of measurement
Spectrophotometer

9

Description
Alkaline phosphatase
Timepoint
Before intervention & week 12 after intervention
Method of measurement
Spectrophotometer

10

Description
Serum Creatinine
Timepoint
Before intervention & week 12 after intervention
Method of measurement
Spectrophotometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: diet for breakfast, lunch, dinner, based on the principles of Traditional Medicine with commands to protect the health based on the principles of Traditional Medicine in the regulation of the habits of sleep and food
Category
Lifestyle

2

Description
Control group: daily diet with commands to protect the health based on the principles of Traditional Medicine in the regulation of the habits of sleep and food

Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hussein Hospital
Full name of responsible person
Mohammad Javad Ehsani Ardekani M.D
Street address
Shahid Madani (north side) St., before the Imam Hussain Square, Imam Hossein Hospital
City
Tehran

2

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Hatami M.D
Street address
Yemen St., Shahid Chamran Highway, Taleghani Hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center, Shahid Behe
Full name of responsible person
Rasool Choopani M.D, Ph.D, Assistant Professor
Street address
No.8 Shams Alley, opposite Tavanir St., Vali Asr Street, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center, Shahid Behe
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin

Type of organization providing the funding
empty

2

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Rasool Choopani M.D

Street address

Yemen St., Shahid Chamran Highway, next to
Taleghani Hospital, Shahid Beheshti University of
Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti University
of Medical Sciences

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

School of Traditional Medicine, Traditional Medicine
and Materia Medica Research Center, Shahid Behe

Full name of responsible person

Rasool Choopani M.D

Position

Ph.D, Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Gastroenterology and Hepatology,
Taleghani Hospital, Shahid Beheshti University of Med

Full name of responsible person

Mohamad Javad Ehsani Ardekani M.D

Position

M.D, Gastroenterologist, Associate Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Jamileh Mahdavi Jafari

Position

Ph.D student of Traditional Medicine

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty
Analytic Code
empty

Data Dictionary
empty