

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of adding angostifolia powder in addition to conventional medical treatment of liver cirrhosis on Levels of inflammatory markers in plasma and liver enzymes

Protocol summary

Evaluation of inflammatory markers and liver enzymes

Study aim

Effect of antioxidants and natural flavonoids in elaeagnus angostifolia to control and reduce the symptoms of patients with cirrhosis in order to reduce the complications of chemical drugs and the cost of treatment for patients.

Design

Randomized parallel clinical trial with two groups of control and intervention with a sample size of 46

Settings and conduct

Patients with liver cirrhosis referring to Motahhari clinic in Shiraz, The study plan will be introduced and if the patients are satisfied and under the supervision of the doctor, the treatment and intervention begins, It takes ten weeks. Patients do the blood test for the examination considerable biomarkers before they begin the intervention and after the intervention. Blind is not done. Each patient will dissolve 15 grams of angostifolia powder or 15 grams of placebo in a glass of water daily and consumes after dinner.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient with liver cirrhosis, age between 18 to 60 years Exclusion criteria: Having an inflammatory or chronic diseases (kidney disease, liver disease, inflammatory bowel disease, heart ischemia, diabetes, lung disease, asthma, cancer, HIV, systemic inflammation and...) , Active gastric bleeding and gastritis ,Pregnancy or lactation at the same time as studying, Drinking alcohol or using narcotic at the same time as studying

Intervention groups

Control group : 15 gr corn starch daily for 10 weeks in addition to conventional medical treatment of liver cirrhosis Intervention group : 15 gr angostifolia powder daily for 10 weeks in addition to conventional medical treatment of liver cirrhosis

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100223003408N4**

Registration date: **2018-12-03, 1397/09/12**

Registration timing: **retrospective**

Last update: **2018-12-03, 1397/09/12**

Update count: **0**

Registration date

2018-12-03, 1397/09/12

Registrant information

Name

Maryam Ekramzadeh

Name of organization / entity

Shiraz University of Medical Sciences, Nutrition Department

Country

Iran (Islamic Republic of)

Phone

+98 917 317 3891

Email address

ekramzadeh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-10-13, 1397/07/21

Actual recruitment start date

2018-06-22, 1397/04/01

Actual recruitment end date

2018-10-13, 1397/07/21

Trial completion date

2018-12-22, 1397/10/01

Scientific title

The effect of adding angostifolia powder in addition to conventional medical treatment of liver cirrhosis on Levels of inflammatory markers in plasma and liver enzymes

Public title

The effect of angostifolia in patients with Cirrhosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Person with Cirrhosis Age between 18 to 60 years

Exclusion criteria:

Diabetes Hypothyroidism or hyperthyroidism Kidney disease Lung disease Cardiovascular disease Smoking Alcohol and tobacco consumption

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization, Individual, Random allocation software, 12 randomization sequence in permuted blocks of size 4 In this study, the allocation of people to the two groups was done using permutational block method. In this method, A represents the person who receives the intervention, and B represents the person who is in the control group. Considering the quadruple block; reversing the AABB code 0, replacing the ABAB code 1, the ABBA code 2, the BAAB code 3, the BBAA code 4, and the BABA code 5 to 9. Then, using the random number table, we select the starting point randomly, followed by 12 rows or columns. Given the order of the numbers of the table, we chime each corresponding number to the number we encountered, for example, if the 3 first digits of the random number table are 1, 0, and 5, respectively. The order of receiving treatment by the first 12 people in both groups will be ABABAABBBABA left to right, respectively. So, finally, by selecting 12 tables from the table, how all 48 people will be assigned will be identified in two groups.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences

Street address

Zand street

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2018-06-15, 1397/03/25

Ethics committee reference number

IR.SUMS.REC.1396.47

Health conditions studied**1****Description of health condition studied**

Liver cirrhosis

ICD-10 code

K74.6

ICD-10 code description

Other and unspecified cirrhosis of liver

Primary outcomes**1****Description**

Tumor necrosis factor-alpha

Timepoint

Before intervention and 10 weeks after intervention

Method of measurement

ELISA

Secondary outcomes**1****Description**

Alanine aminotransferase

Timepoint

Before intervention and 10 weeks after intervention

Method of measurement

ALT Kit

2

Description

Aspartate transaminase

Timepoint

Before intervention and 10 weeks after intervention

Method of measurement

AST Kit

Intervention groups

1

Description

Control group : 15gr corn starch with 1glass water daily for 10 weeks in addition to conventional medical treatment of liver cirrhosis

Category

Treatment - Drugs

2

Description

Intervention group :15gr angostifolia powder with 1 glass water daily for 10 weeks in addition to conventional medical treatment of liver cirrhosis

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic Cirrhosis Motahari

Full name of responsible person

Soheila Rahimi

Street address

Namazi Squire

City

Shiraz

Province

Fars

Postal code

71876-56895

Phone

+98 71 3612 1000

Email

Soheila.rhm17@gmail.com

2

Recruitment center

Name of recruitment center

Motahari Clinic

Full name of responsible person

Dr Mahvash Alizadeh Naeeni

Street address

Zand Street

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 3612 1000

Email

Soheila.rhm17@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Ekramzadeh

Street address

Zand Ave.

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3235 2559

Email

President@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Ekramzadeh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Razi Blvd
City
Shiraz
Province
Fars
Postal code
71536-75541
Phone
+98 71 3725 1001
Fax
+98 71 5367 5541
Email
Ekramzadeh@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Ekramzadeh
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Razi Blvd
City
Shiraz
Province
Fars
Postal code
71536-75541
Phone
+98 71 3725 1001
Email
Ekramzadeh@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences
Full name of responsible person
Soheila Rahimi
Position
Master Student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Razi Blvd.
City
Shiraz
Province
Fars
Postal code
71536-75541
Phone
+98 71 3725 1001
Email
Soheila.rhm17@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available