Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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 consums 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

Evaluation of inflammatory markers and liver enzymes

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

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Maryam Ekramzadeh
Name of organization / entity
Shiraz University of Medical Sciences, Nutrition Department
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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
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71876-56895
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2

Recruitment center
Name of recruitment center
Motahari Clinic
Full name of responsible person
Dr Mahvash Alizadeh Naeeni
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Master Student
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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