Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

The Effect of Berberis Vulgaris Fruits Extract on Alanine Aminotransfrase ,Aspartate Aminotransfrase,Serum Lipid and Fasting Blood Glucose of Non-Alcoholic Steatohepatitis in Patients Referred to Clinic Martyr Motahhari Shiraz in 1390

Protocol summary

Summary

The aim of this clinical trial is to study the effect of Berberis Vulgaris on non alcoholic steatohepatitis in patients with nonalcoholic fatty liver disease. in Design of This Study 80 patients will be included That major including criteria are : older than 20 years with nonalcoholic-fatty liver disease and liver enzymes> 42 and proportion of ALT/ AST> 1. The fatty liver will be recognized by sonography. Exclusion criteria are : using drugs that affect liver tests during the last 2 , viral hepatitis, hemochromatosis, autoimmune hepatitis, cirrhosis,Type 1 diabetes , Alcohol dependency, Pregnancy,Breast feeding, and Infectious diseases.in Intervention : Intervention group will be administrated 750 mg of Berberis Vulgaris Fruits Extract BID during 3 month and control group will be given placebo. main outcomes are : Liver enzymes and fasting blood sugar That will be assessed Before, after 45 days and 3 months of treatment course, tri glycirid, total cholestrol, LDL and HDL Will be Measured Before and End of Study. be

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202068505N2**
Registration date: **2012-09-20, 1391/06/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-09-20, 1391/06/30

Registrant information

Name

Seyed Saeed Najafi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1727 7445

Email address

najafisa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology of Shiraz university of medical sciences

Expected recruitment start date

2011-07-28, 1390/05/06

Expected recruitment end date

2012-01-26, 1390/11/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Berberis Vulgaris Fruits Extract on Alanine Aminotransfrase ,Aspartate Aminotransfrase,Serum Lipid and Fasting Blood Glucose of Non-Alcoholic Steatohepatitis in Patients Referred to Clinic Martyr Motahhari Shiraz in 1390

Public title

Effect of Barberry on Non Alcoholic

Purpose

Treatment

Inclusion/Exclusion criteria
Including criteria : older than 20 years with nonalcoholic-fatty liver disease; liver enzymes>42 and proportion of ALT/ AST>1. Excluding criteria : using drugs that affect liver tests during the last 2 months; viral hepatitis; hemochromatosis; autoimmune hepatitis; cirrhosis;type 1 diabetes; alcohol dependency; pregnancy; breast feeding and infectious diseases
Age
From **20 years** old to **60 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)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Commitee of Shiraz University of Medical Scineces
Street address
Seventh Floor of Shiraz University of Medical Sciences and Health Services, Next to red crescent organazation, Zand blvd
City
Shiraz
Postal code
Approval date
2012-04-03, 1391/01/15
Ethics committee reference number
CT-91-6081

Health conditions studied

1

Description of health condition studied
Non-alcoholic Steatohepatitis
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
ALT
Timepoint
Before, 45 days and 3 month after the therapy
Method of measurement
Laboratory

2

Description
AST
Timepoint
Before, 45 days and 3 month after the therapy
Method of measurement
Laboratory

3

Description
FBS
Timepoint
Before, 45 days and 3 month after the therapy
Method of measurement
Laboratory

Secondary outcomes

1

Description
Chol-T
Timepoint
Before and 3 months after the therapy
Method of measurement
laboratory

2

Description
Triglycirid
Timepoint
Before and 3 months after the therapy
Method of measurement
laboratory

3

Description
LDL
Timepoint
Before and 3 months after the therapy
Method of measurement
laboratory

4

Description
HDL
Timepoint
Before and 3 months after the therapy
Method of measurement
laboratory

Intervention groups

1

Description
Intervention group : 750 mg of Berberis Vulgaris Fruits Extract, BID during 3 months
Category
Treatment - Drugs

2

Description
Control group : placebo, with same shape, color and packaging without active drug.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahary Polyclinic
Full name of responsible person
Dr; Ali Jangju
Street address
Zand Street, Namazi Square
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Shiraz University of Medical Sciences
Full name of responsible person
Dr Gholamreza Hatam
Street address
Seventh Floor of Shiraz university of Medical Sciences and Health Services, Next to Red Crescent Organazation, Zand blvd
City
Shiraz
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, Shiraz University of Medical Sciences
Proportion provided by this source
100
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
Shiraz University of Medical Sciences
Full name of responsible person
Raziye Iloun Kashkooli
Position
MSc.Student of Nursing
Other areas of specialty/work
Street address
No 7179617474, Sarv Street, Baharan Town, Shiraz
City
Shiraz
Postal code
7179617474
Phone
+98 71 1840 3755
Fax
Email
raziiloon@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Science
Full name of responsible person
Dr Seyed Kazem Hosseini Asl
Position
Associate Professor of Gastroenterology and Hepatology
Other areas of specialty/work
Street address
Namazi Hospital, Zand Street, Namazi Square, Shiraz
City
Shiraz
Postal code
11351-71937
Phone
+98 71 1212 5610
Fax
Email
hoseiniasl@sums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Raziye Iloun Kashkooli

Position

Other areas of specialty/work

Street address

No 7179617474, Sarv Street, Baharan Town, Shiraz

City

Shiraz

Postal code

7179617474

Phone

+98 71 1840 3755

Fax

Email

raziiloon@yahoo.com

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