

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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 glycid, 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

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Iran (Islamic Republic of)

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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 Committee of Shiraz University of Medical Sciences

Street address

Seventh Floor of Shiraz University of Medical Sciences and Health Services, Next to red crescent organization, 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

Triglycerid

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 Organization, 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

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Position

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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