

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparing the effect of combined extract of *Fumaria parviflora*, *Salix aegyptiaca*, *Taraxacum officinale*, *Coriandrum sativum* L versus Vit E on liver enzymes level in patients with fatty liver disease

Protocol summary

Summary

The aim of the study is evaluating the effect of combined extract of *Fumaria parviflora*, *Salix aegyptiaca*, *Taraxacum officinale*, *Coriandrum sativum* L. on fatty liver disease. This is a clinical trial study. Inclusion criteria: AST, ALT more than 1.5 equivalents of normal range plus sonographic confirmation; from 20 to 60 years old. Exclusion criteria: Taking drugs before or at the time of intervention that could affect liver function tests; Pregnancy or breastfeeding; Younger than 20 or older than 60 years old. Target sample size: 82. We selected patients included inclusions criteria in our study (We ignored the degree of fatty liver diseases and The criterion is to improve it at any grade) under consideration of exclusion criteria. We explained aim and method of the study at first and then patients were divided into two groups: vit E user and herbal extract user, then they used drugs (100 ML of herbal extract twice a day and 40 Mg vit E daily) for 40 days and then we tested TG, FBS, CHOL, AST, ALT and signs (right upper quadrants pain) for evaluating effect of drugs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082935963N1**
Registration date: **2017-10-30, 1396/08/08**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-30, 1396/08/08

Registrant information

Name

Ehsan Sahbayi

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Sabzevar University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of combined extract of *Fumaria parviflora*, *Salix aegyptiaca*, *Taraxacum officinale*, *Coriandrum sativum* L versus Vit E on liver enzymes level in patients with fatty liver disease

Public title

Effect of herbal extracts on fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: AST, ALT more than 1.5 equivalents of normal range plus sonographic confirmation; from 20 to

60 years old Exclusion criteria : alcoholic drinks user(now or in past); being athlete; hospitalized; Acute or chronic disease before or at the time of intervention that can affects liver function tests; Taking drugs before or at the time of intervention that could affects liver function tests; Pregnancy or breastfeeding; Younger than 20 or older than 60 years old

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: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University of medical science

Street address

asadabadi street, central site of Sabzevar University of Medical Sciences

City

sabzevar

Postal code

Approval date

2016-09-22, 1395/07/01

Ethics committee reference number

IR.MEDSAB.REC.1395.153

Health conditions studied

1

Description of health condition studied

fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Aminotransferases

Timepoint

1-3 days before intervention and 40 days after intervention

Method of measurement

U/L

Secondary outcomes

1

Description

Cholestrol

Timepoint

1-3 days before intervention and 40 days after the intervention

Method of measurement

Mg/dl

2

Description

Triglyceride

Timepoint

1-3 days before intervention and 40 days after the intervention

Method of measurement

Mg/dl

3

Description

Fasting blood sugar

Timepoint

1-3 days before intervention and 40 days after the intervention

Method of measurement

Mg/dl

Intervention groups

1

Description

Intervention group 1: Comparison of effectiveness of combined extract of Fumaria parviflora, Salix aegyptiaca, Taraxacum officinale ,Coriandrum sativum L. 100 ml BID

Category

Treatment - Drugs

2

Description

Intervention group 2: vit E 400 mg daily

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

GI clinic of vasei sabzevar

Full name of responsible person**Street address****City**

sabzevar

Sponsors / Funding sources1**Sponsor****Name of organization / entity**Vice Chancellor for research of Sabzevar University of
Medicine Sciences**Full name of responsible person**

research university unit

Street addressAsadabadi Street, Central Site of Sabzevar University
of Medical Sciences**City**

sabzevar

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding sourceVice Chancellor for research of Sabzevar University of
Medicine 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**

Sabzevar University of Medical Sciences

Full name of responsible person

Ehsan sahbayi Ejlali

Position

Intern(in medicine science)

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inquiries****Contact****Name of organization / entity**

sabzevar medical science university

Full name of responsible person

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Sabzevar University Of Medical Sciences

Full name of responsible person

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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