Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 2026

The effect of Matricaria chamomilla L. on insulin resistance, inflammatory status and other related indices in patients with non-alcoholic fatty liver

Protocol summary

Study aim
To determine the effect of chamomile consumtion on non-alcoholic fatty liver

Design
In this study 44 eligible patients will attend.This double-blind, randomized clinical trial has two groups of intervention and control in parallel.

Settings and conduct
This study is a double blind clinical trial that screening will be done at Fasa University of Medical Sciences Health centers. All patients, physicians and statisticians are unaware of the type of medicine or placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1-Diagnosis of fatty liver and steatohepatitis with: A- serum level of Alanine Transaminease (ALT) More than one and a half times the highest normal limit and, the amount of aspartate transaminase (AST) In both sexes is greater than 30 units per liter. B- Diagnosis of fatty liver in liver ultrasound 2-The patient have not to consume some drugs like silybin, ursodeoxycholic acid, Polyene Phosphatidylcholine, vitamin E and other medicines or Medicinal herbs with blood lipid regulation effect and hepatoprotective effect from four weeks bfore entering to the study. exclusion criteria:1-pregnancy and lactation 2-Liver diseases such as Liver failure,autoimmune hepatitis, viral hepatitis B and C (active or inactive), and etc.3-Hypo and hyperthyroidism 4-Any malignancy (treated or not)5-Taking warfarin 6-Taking contraceptives, ouroso-doxycyclic acid, glucocorticoid, statins, probiotics, vitamin E over the past three months 7-Chamomile allergy history

Intervention groups
Patients are divided into two groups of 22.the first group is given chamomile and control group is given placebo.The medication and placebo are 500 mg capsules that will be used two items in fasting morning and two items before bedtime for three months.

Main outcome variables
Degree of fatty liver; Aminotransferase levels; Insulin resistance, lipid profiles

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180903040941N1**
Registration date: **2019-06-03, 1398/03/13**
Registration timing: **prospective**

Last update: **2019-06-03, 1398/03/13**
Update count: **0**

Registration date
2019-06-03, 1398/03/13

Registrant information

Name
sadegh amiri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3672 3826

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sadeghamiri2877@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-05, 1398/03/15

Expected recruitment end date
2020-04-20, 1399/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Matricaria chamomilla L. on insulin resistance, inflammatory status and other related indices in patients with non-alcoholic fatty liver

Public title
To evaluate effects of Matricaria chamomilla L. on patients with non alcoholic fatty liver disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
sign the consent form age between 25-65 years BMI between 22-35 Diagnosis of fatty liver and steatohepatitis with: A- serum level of Alanine Transaminease (ALT) More than one and a half times the highest normal limit(66/5000This means that more than 45 men and women more than or equal to 29 units per liter)Also, the amount of aspartate transaminase (AST) In both sexes is greater than 30 units per liter(According to the latest definition of ALT and abnormal AST in men and women). B- Diagnosis of fatty liver (moderate to high) in liver ultrasound. The patient have not to consume lipid regulating drugs for four weeks The patient have not to consume some drugs like silybin, ursodeoxycholic acid, Polyene Phosphatidylcholine, vitamin E and Medicinal herbs with blood lipid regulation effect and hepatoprotective effect from four weeks bfore entering to the study.

Exclusion criteria:
pregnancy and lactation Liver failure (acute or chronic) Liver diseases such as autoimmune hepatitis, viral hepatitis B and C (active or inactive), Wilson's disease and etc. Hypo and hyperthyroidism Renal failure (creatinine above 1.5 mg / dL) Any malignancy (treated or not) Taking warfarin Addiction and alcohol consumption Taking contraceptives, ouroso-doxycyclic acid, glucocorticoid, statins, probiotics, vitamin E over the past three months Chamomile allergy history

Age
From **25 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Simple randomization Random unit: Individual Randomization Tool: Random Numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and researchers will not be aware of the study groups. Drug capsules and placebo capsules are also similar to each other and they are only labeled A and B.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of fasa university of medical science

Street address
Ibn Sina Square, Fasa University of Medical Sciences

City
Fasa

Province
Fars

Postal code
7461686688

Approval date
2019-02-17, 1397/11/28

Ethics committee reference number
IR.FUMS.REC.1397.150

Health conditions studied

1

Description of health condition studied
non alcoholic fatty liver

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Fatty liver grade

Timepoint
Initially and three months later

Method of measurement
Ultrasound

2

Description

Hepatic aminotransferases

Timepoint

Initially and six weeks later and three months later

Method of measurement

Laboratory Kit

3

Description

Fatty liver index(FLI)

Timepoint

Initially and three months later

Method of measurement

Using formula: [e 0.953*loge (triglycerides) + 0.139*BMI + 0.718*loge (ggt) + 0.053*waist circumference - 15.745) / (1 + e 0.953*loge (triglycerides) + 0.139*BMI + 0.718*loge (ggt) + 0.053*waist circumference - 15.745)] × 100

4

Description

Alpha Tumor Necrosis Factor

Timepoint

Initially and three months later

Method of measurement

Laboratory Kit

5

Description

Insulin resistance index

Timepoint

Initially and three months later

Method of measurement

Calculate the HOMA-IR

6

Description

Alkaline phosphatase

Timepoint

initially and three months later

Method of measurement

Laboratory Kit

Secondary outcomes

1

Description

Body mass composition

Timepoint

At the entrance and three months later

Method of measurement

Body mass composition machine

2

Description

Inflammation

Timepoint

At the entrance and three months later

Method of measurement

hs-CRP labratory kit

3

Description

Lipide profile

Timepoint

At the entrance and three months later

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group: A capsule containing 500 mg of chamomile flower powder will be taken four times a day, two fasting morning and two nights before bedtime for three months.

Category

Treatment - Drugs

2

Description

Control group: placebo capsules containing roasted wheat flour plus 50 mg of chamomile powder will be taken four times a day, two fasting morning and two nights before bedtime for three months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali asr hospital

Full name of responsible person

Sadegh amiri

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
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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
Fasa 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
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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