Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Aug 2026

Effect of saffron powder on serum concentration of hs-CRP, TNF-α, MDA, TAC, adiponectin and leptin in patients with non-alcoholic fatty live disease

Protocol summary

Summary

The present study is a double blind clinical trial. After approving the research in the ethics committee of the Vice-Chancellor of Research and Technology of Iran University of Medical Sciences and obtaining necessary permits, the participants from among the patients referred to Gastroenterology clinic of Rasoul-e-Akram Medical Center, That are based on liver ultrasound and blood tests, non-alcoholic fatty liver in them, who are willing to cooperate and enter the study, are selected and after explaining all stages of the research project and signing the consent form enter the design be. At the beginning of the study, 15 cc of venous blood from patients will be taken after 10-12 hours of fasting, which will be freeze After separating the serum, it is freeze at -80 ° C,. Public data forms (age, sex , Height, weight, BMI, waist circumference, hip circumference, smoking, duration of disease, fatty liver severity, blood pressure, etc.), the 24-hour recall of the feed and the IPAQ physical activity questionnaire are completed, as well as the patients Body fat percentage will be evaluated with ebody. At the end of the research, forms and measurements will be carried out again. Also, the weight loss regimen is individually adjusted for each person at the beginning of the study. Regarding the protocol for treating non-alcoholic fatty liver, a physical activity of 30 minutes, one day is recommended. Participants will be randomly divided into two groups: 1- An intervention group consisting of 38 males and females with non-alcoholic fatty liver who will receive 100 mg of saffron for 12 weeks during the study; . 2. Control group of Includes 38 males and females with non-alcoholic fatty liver that will be treated with placebo tablets containing dextrose malto during the intervention. The placebo will be in any shape, size, and color, and the packaging indistinguishable from saffron tablets. Inclusion criteria 1- Age 18 to 65 years 2. Both sexes 3. Detection of non-alcoholic fatty liver by an expert physician based on the high levels of ALT, AST enzymes >=30U / L in men and> 19U/L in women) and liver transcription 4. Desire to participate in studying and signing conscientious intention Non-inclusion criteria: (exclusion criteria) 1- Pregnancy and lactation or planning pregnancy 2- Use an antioxidant supplement or any nutritional supplement within one month before sampling 3. Acute heart disease, kidney, thyroid, diabetes, infections, hepatitis B and C and other liver diseases (diagnosed by a specialist) and diseases that affect the weight (hyperprolactinemia, Cushing's syndrome) 4. Have a high-gain or weight loss regimen within 3 months prior to sampling 5- Using effective drugs on weight, fatty liver and insulin resistance during 3 months before sampling (hormonal, antidepressant, anti-psychotics) 6- Use of drugs that are probably related to NAFLD: 7- (valporic acid, tetracycline, systematic glucocorticoid, methotrexate amidarone, anabolic steroids, estrogen, tamoxifen or other known hepatotoxic drugs) Exit criteria: 1. Unwillingness to continue cooperation in research 2- Initiating the use of anti-NASH drugs (thiazolidindiones, vitamin E, betaine, milk thistle, UDCA, SAM-E, gemfibrozil, probiotic, anti-TNF-α) 3. Start using any type of nutritional supplement and anti-inflammatory drugs 4. Cure for diseases that require special treatments that interfere with the intervention. 5- Pregnancy during the study 6- Patients whose compliance and consumption of saffron powder or placebo by them is less than 80% recommended by the host. Applied Objectives: If the effect of saffron powder on hs-CRP TNF-α, MDA, TAC, body composition, adiponectin and leptin (inflammatory and oxidative stress markers, body composition and adipokines) can be used as an auxiliary substance in Along with other treatments to improve disorders in patients with non-alcoholic fatty liver

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705309472N13**
Registration date: **2017-07-26, 1396/05/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-07-26, 1396/05/04

Registrant information

Name

Naheed Aryaeian

Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Governmental/ iran university of medical science

Expected recruitment start date

2017-02-18, 1395/11/30

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of saffron powder on serum concentration of hs-CRP, TNF-α, MDA, TAC, adiponectin and leptin in patients with non-alcoholic fatty live disease

Public title

Effect of saffron on inflammatory and antioxidant factors in patients with fatty liver disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria 1- Age 18 to 65 years 2. Both sexes 3. Detection of non-alcoholic fatty liver by an expert physician based on the high levels of ALT, AST enzymes >=30U / L in men and> 19U/L in women) and liver transcription 4. Desire to participate in studying and signing conscientious intention Non-inclusion criteria: (exclusion criteria) 1- Pregnancy and lactation or planning pregnancy 2- Use an antioxidant supplement or any nutritional supplement within one month before sampling 3. Acute heart disease, kidney, thyroid, diabetes, infections, hepatitis B and C and other liver diseases (diagnosed by a specialist) and diseases that affect the weight (hyperprolactinemia, Cushing's syndrome) 4. Have a high-gain or weight loss regimen within 3 months prior to sampling 5- Using effective drugs on weight, fatty liver and insulin resistance during 3 months before sampling (hormonal, antidepressant, anti-psychotics) 6- Use of drugs that are probably related to NAFLD: 7- (valporic acid, tetracycline, systematic glucocorticoid, methotrexate amidarone, anabolic steroids, estrogen, tamoxifen or other known hepatotoxic drugs) Exit criteria: 1. Unwillingness to continue cooperation in research 2- Initiating the use of anti-NASH drugs (thiazolidindiones, vitamin E, betaine, milk thistle, UDCA, SAM-E, gemfibrozil, probiotic, anti-TNF-α) 3. Start using any type of nutritional supplement and anti-inflammatory drugs 4. Cure for diseases that require special treatments that interfere with the intervention. 5- Pregnancy during the study 6- Patients whose compliance and consumption of saffron powder or placebo by them is less than 80% recommended by the host.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Iran University of Medical Sciences

Street address

Shahid Hemmat Highway intersection of Sheikh Fazlollah and Shahid Chamran Iran University of Medical Sciences

City

tehran

Postal code

Approval date
2017-02-19, 1395/12/01
Ethics committee reference number
IR.IUMS.REC 1395.9411468008

Health conditions studied

1

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

Primary outcomes

1

Description
hs-crp
Timepoint
Before intervention and 3 months after intervention
Method of measurement
ELISA kit in ng / ml

2

Description
ALT
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Enzymatic photometric

3

Description
AST
Timepoint
Before intervention and 3 months after intervention
Method of measurement
Enzymatic photometric

Secondary outcomes

1

Description
Waist to hip ratio (WHR)
Timepoint
Before the intervention and three months after the intervention
Method of measurement
calculation

2

Description
TNF-a
Timepoint
Before the intervention and three months after the intervention
Method of measurement
ELISA kit in pg / ml

3

Description
TAC
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Using the kits and colorimetric method in umol / L

4

Description
adiponectin
Timepoint
Before the intervention and three months after the intervention
Method of measurement
ELISA kit in ng / ml

5

Description
leptin
Timepoint
Before the intervention and three months after the intervention
Method of measurement
ELISA kit in ng / ml

6

Description
Malondialdehyde (MDA)
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Colorimetric method ng / ml

7

Description
weight
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Digital scale in kilograms

8

Description
body mass index (BMI)
Timepoint
Before the intervention and three months after the intervention
Method of measurement

Calculation / in kg / m2

9

Description
Waist
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Meter in cm

10

Description
Hip circumference
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Meter in cm

11

Description
Body fat percentage
Timepoint
Before the intervention and three months after the intervention
Method of measurement
ebody device BIA method

Intervention groups

1

Description
Saffron powder group: One day, one tablet will contain 100 mg of saffron for 3 months (12 weeks).
Category
Treatment - Drugs

2

Description
Placebo group: For a period of 3 months (12 weeks), one tablet will contain 100 mg dextrose malto.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
hazrat rasool akram hospital
Full name of responsible person
farnaz kaviani pour
Street address
Shahid Hemmat Highway intersection of Sheikh Fazlollah and Shahid Chamran Iran University of Medical Sciences School of Public Health
City
tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research of Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed Ali Javad Mousavi: Deputy of Research and Technology of Iran University of Medical Science
Street address
Shahid Hemmat highway, intersection of Sheikh Fazlollah and Chamran, Iran University of Medical Sciences
City
tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research of Iran 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
Iran University of Medical Sciences
Full name of responsible person
Dr naheed aryaeian
Position
nutrition PHD
Other areas of specialty/work
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Person responsible for updating data

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farnaz kaviani pour

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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