Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Aug 2026

The effect of saffron supplementation on liver enzymes, insulin resistance, lipid profile and The degree of hepatic steatosis in patients with non-alcoholic fatty liver disease: a randomised, double-blind, placebo-controlled study.

Protocol summary

Summary

Objective: The effect of supplementation with saffron powder compared with placebo on liver enzymes, insulin resistance, blood lipids and liver steatosis in patients with NAFLD. Study: randomized double blind clinical trial. The study population:Women and men with Nonalcoholic Fatty Liver disease referring to Liver and Digestive clinic of Rasoul Akram hospital. sample of people who desire to participate and have their inclusion criteria are selected. Inclusion criteria : both sexes ; aged between 18 and 65 years; diagnosis of NAFLD by a physician; according to the high enzyme ALT, AST (> U / L 30 in men and> U / L 19 in women) and liver ultrasonography ;willingness to participate in the study and signed a letter of conscious satisfaction. Exclusion criteria: pregnancy and breastfeeding and those trying to conceive; The use of antioxidant supplements during the month before sampling; severe heart disease, kidney, thyroid, diabetes, infections, hepatitis B, C and other liver diseases (diagnosis by liver specialist doctors) and diseases that affect on weight ;Severe lose weight or Weight gain dieting During the 3 months prior to sampling ;The use of effective drugs against weight during the three months prior to sampling; use of drugs that may be associated with NAFLD; unwillingness to continue the study; The introduction of the anti-NASH; disease that require special treatment and intervention disrupts the process; pregnancy during the study ; Patients' acceptance of (compliance) and saffron powder or placebo by their consumption levels recommended by the Executive is less than 80%. Intervention: 38 patients in the group receiving saffron powder (containing 100 mg of saffron) and 38 patients receiving placebo (maltodextrin). Intervention duration: 12 weeks. The outcome of the study: factors including ALT, AST, GGT, lipid profile TC, TG, HDL, LDL, glucose and fasting insulin, insulin resistance index, quantitative index of insulin sensitivity, direct and total bilirubin, apolipoprotein a1 and the degree of fibrosis and hepatic steatosis will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201610269472N11**
Registration date: **2016-11-22, 1395/09/02**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-11-22, 1395/09/02

Registrant information

Name

Naheed Aryaeian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

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
The effect of saffron supplementation on liver enzymes, insulin resistance, lipid profile and The degree of hepatic steatosis in patients with non-alcoholic fatty liver disease: a randomised, double-blind, placebo-controlled study.

Public title
The effect of saffron supplementation on liver enzymes, insulin resistance, lipid profile and The degree of hepatic steatosis in patients with non-alcoholic fatty liver disease: a randomised, double-blind, placebo-controlled study.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria : both sexes ؛ aged between 18 and 65 years ؛ diagnosis of NAFLD by a physician, according to the high enzyme ALT, AST (> U / L 30 in men and> U / L 19 in women) and liver ultrasonography ؛ willingness to participate in the study and signed a letter of conscious satisfaction. Exclusion criteria: pregnancy and breastfeeding and those trying to conceive; The use of antioxidant supplements during the month before sampling; severe heart disease, kidney, thyroid, diabetes, infections, hepatitis B, C and other liver diseases (diagnosis by liver specialist doctors) and diseases that affect on weight (hyperprolactinemia, Cushing's syndrome) ;Severe lose weight or Weight gain dieting During the 3 months prior to sampling ;The use of effective drugs against weight during the three months prior to sampling (steroids, antidepressants, antipsychotics); use of drugs that may be associated with NAFLD (glucocorticoid, methotrexate, amidarone systemic, tetracycline, valporic acid anabolic steroids, estrogen, tamoxifen, or other known hepatotoxic); unwillingness to continue the study; The introduction of the anti-NASH (vitamin E, thiazolidindiones milkthistle, betaine, SAM-E, UDCA, gemfibrozil,, Anti-TNF-α, probiotic) ; disease that require special treatment and intervention disrupts the process; pregnancy during the study ; Patients' acceptance of (compliance) and saffron powder or placebo by their consumption levels recommended by the Executive is less than 80%.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
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
Iran University of Medical Sciences , The intersection of Sheikh Fazlallah and Shahid Chamran, Shahid Hemman highway
City
tehran
Postal code
Approval date
2016-11-08, 1395/08/18
Ethics committee reference number
IR.IUMS.REC 1395.9321323007

Health conditions studied

1

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

Primary outcomes

1

Description
ALT
Timepoint
Before intervention and 12 weak after intervention
Method of measurement
Enzymatic photometry

2

Description

AST

Timepoint

Before intervention and 12 weak after intervention

Method of measurement

Enzymatic photometry

Secondary outcomes

1

Description

apo a1

Timepoint

Before intervention and three months after intervention

Method of measurement

Immunoturbidometry

2

Description

FBS

Timepoint

Before intervention and three months after intervention

Method of measurement

Enzymatic photometry

3

Description

GGT

Timepoint

Before intervention and three months after intervention

Method of measurement

Enzymatic photometry

4

Description

Insulin

Timepoint

Before intervention and 12 weak after intervention

Method of measurement

ELISA

5

Description

insulin resistance

Timepoint

Before intervention and 12 weak after intervention

Method of measurement

calculation

6

Description

quicki index

Timepoint

Before intervention and 12 weak after intervention

Method of measurement

calculation

7

Description

lipid profile(LDL-c, HDL-c, TG, total cholestrol)

Timepoint

Before intervention and three months after intervention

Method of measurement

Enzymatic photometry(LDL by calculation)

8

Description

systolic and diastolic blood pressure

Timepoint

Before intervention and 12 weak after intervention

Method of measurement

Mercury sphygmomanometer

9

Description

sleep quality

Timepoint

Before intervention and 12 weak after intervention

Method of measurement

The Pittsburgh Sleep Quality questionnaire

10

Description

life quality

Timepoint

Before intervention and 12 weak after intervention

Method of measurement

quality of life sf 12 questionnaire

11

Description

Hepatic steatosis

Timepoint

Before intervention and 12 weak after intervention

Method of measurement

ultrasonography.

12

Description

Liver fibrosis

Timepoint

Before intervention and 12 weak after intervention

Method of measurement

fibroscan

13

Description

Direct bilirubin and total bilirubin

Timepoint

Before intervention and three months after intervention

Method of measurement

Enzymatic photometry

Intervention groups

1

Description
Intervention group: receiving one pill containing 100 mg powder of Saffron daily with meal for 12 weak.
Category
Treatment - Drugs

2

Description
Placebo group: receiving one pill containing 100 mg maltodextrin daily with meal for12 weak.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat -e Rasool General Hospital
Full name of responsible person
Reyhaneh Sadat Mirnasrollahi Parsa
Street address
School of Public Health,Iran University of Medical Sciences,The intersection Sheikh Fazlallah and Shahid Chamran,Shahid Hemmat highway
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research Iran University of Medical Sciences
Full name of responsible person
Dr Ali Javad Moosavi,Assistant of Research and Technology,Iran University of Medical Sciences
Street address
Iran University of Medical Sciences,The intersection of Sheikh Fazlallah and Shahid Chamran,Shahid Hemmat highway
City
tehran
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 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 Nahid Aryaeian
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Other areas of specialty/work
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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Reyhaneh Sadat Mirnasrollahi Parsa

Position

MS Student in Health Sciences in Nutrition

Other areas of specialty/work

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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