Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Evaluation of the effect of Crocin on the serum levels of liver enzymes and Lipid Profile in patients with non-alcoholic fatty liver disease

Protocol summary

Study aim
Treatment of NAFLD patient by Crocin with low adverse effects
Design
A double blind randomized placebo-controlled trial of Crocin on patient with NAFLD.
Settings and conduct
Imam Hospital, Ahvaz
Participants/Inclusion and exclusion criteria
Inclusion criteria: both sexes, liver ultrasonography, high liver enzyme ALT and AST, >18 years old patient with NAFLD. Exclusion criteria: Viral and autoimmune liver diseases, metabolic liver disease, drug and alcohol consumption, pharmacotherapy in NAFLD.
Intervention groups
30 patients in the group receiving Crocin tablet (Krocina 15 mg) and 30 patients receiving placebo (maltodextrin) for 8 weeks.
Main outcome variables
Treatment of NAFLD and improvement of liver enzyme and lipid profile

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180513039634N1**
Registration date: **2018-06-13, 1397/03/23**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-13, 1397/03/23**
Update count: **0**
Registration date
2018-06-13, 1397/03/23

Registrant information
Name
Behnam Ghorbanzadeh
Name of organization / entity
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Iran (Islamic Republic of)
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+98 61 3391 3635
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-05-26, 1397/03/05
Expected recruitment end date
2018-08-21, 1397/05/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Crocin on the serum levels of liver enzymes and Lipid Profile in patients with non-alcoholic fatty liver disease

Public title
Effect of Crocin on non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
> 18 years old Patient with NAFLD (according to ultrasonography and high level of AST and ALT)
Exclusion criteria:
Viral and autoimmune hepatitis Metabolic liver disease, alcohol and drug consumption Pharmacotherapy for NAFLD
Age

From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
To maintain the double-blinded condition of the study design, labeled study medications using participant identification numbers. At the end of study, statistical analysis was performed using this data (unknown drug by statistics)

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
No. 33, West kianpars, Streest 20

City
Ahvaz

Province
Khouzestan

Postal code
6155893814

Approval date
2018-02-24, 1396/12/05

Ethics committee reference number
IR.AJUMS.REC.1396.1014

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
ALT

Timepoint
Before intervention and 8 weak after intervention

Method of measurement
Enzymatic photometery

2

Description
AST

Timepoint
Before intervention and 8 weak after intervention

Method of measurement
Enzymatic photometery

3

Description
TC, TG, LDL, HDL

Timepoint
Before intervention and 8 weak after intervention

Method of measurement
Enzymatic photometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: receiving one tablet containing 15 mg of Crocin (Samisaz Pharmaceutical Co.) daily with meal for 8 weaks.

Category
Treatment - Drugs

2

Description
Control group: receiving one tablet placebo (maltodextrin) daily with meal for 8 weaks.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Hospital
Full name of responsible person
Abazar Parsi
Street address
Imam Hospital, Naderi Street
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6134914971
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Abazar parsi
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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
Ahvaz 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
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Abazar Parsi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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