

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3391 3635

##### Email address

ghorbanzadeh.b@dums.ac.ir

##### 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 photometry

**2**

**Description**

AST

**Timepoint**

Before intervention and 8 weak after intervention

**Method of measurement**

Enzymatic photometry

**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 weeks.

**Category**

Treatment - Drugs

**2**

**Description**

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

**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

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6134914971

**Phone**

+98 61 3391 3635

**Email**

Ghorbanzadeh.b@dums.ac.ir

**Full name of responsible person**

Abazar Parsi

**Position**

Assistant professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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b\_ghorbanzadeh82@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Abazar parsi

**Street address**

Imam Hospital, Departement of internal medicine

**City**

Ahvaz

**Province**

Khuzestan

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**Email**

Ghorbanzadeh.b@dums.ac.ir

**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

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant professor

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Ahvaz University of Medical Sciences

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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