

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of atorvastatin effect on disease severity and quality of life in ulcerative colitis patients.

Protocol summary

Study aim

Evaluation of efficacy of atorvastatin on calprotectin in patients with ulcerative colitis.

Design

40 patients will randomly divided into intervention and control groups. 20 patient will participate in each group. the study will be performed as a phase 2 double-blind, placebo-controlled clinical trial. random sequence was obtained using the online software available on the www.sealedenvelope.com website.

Settings and conduct

In this study patients with ulcerative colitis in GI clinic of BouAli hospital in Tehran,Iran who met inclusion criteria will randomly divided in two groups of placebo and treatment. each group consist of twenty patients. all patients will receive standard treatments. Treatment group will receive 40mg Atorvastatin once daily and placebo group will receive placebo tablets once daily. At the beginning of study and day 60 quality of life questionnaire, and disease severity questionnaire, blood samples for assessment of CRP and ESR, and stool samples for the analysis of Stool Calprotectin will be taken. Drug and placebo will be filled in identical containers by a third person, each container will have a unique code. The researcher, physician and patients are not aware of the allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ulcerative colitis patients in the remission phase, age between 18-65 years old Exclusion criteria: patients under 18 and over 65 years old, sensitivity to statins and pregnant and lactating women.

Intervention groups

Intervention group: patients will receive one atorvastatin 40mg tablet daily for 6 months. Control group: patients will receive one placebo tablet daily for 6 months.

Main outcome variables

Calprotectin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210713051878N1**

Registration date: **2022-09-08, 1401/06/17**

Registration timing: **retrospective**

Last update: **2022-09-08, 1401/06/17**

Update count: **0**

Registration date

2022-09-08, 1401/06/17

Registrant information

Name

Babak Baniadam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3669 9468

Email address

babakba1374@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-22, 1400/05/31

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of atorvastatin effect on disease severity and quality of life in ulcerative colitis patients.

Public title
Atorvastatin effect on ulcerative colitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients in remission phase of ulcerative colitis Age of between 18-65 Informed Consent
Exclusion criteria:
 Pregnancy Lactation History of statin sensitivity

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

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
 Target sample size: **40**
 More than 1 sample in each individual
 Number of samples in each individual: **3**
 Stool calprotectin, ESR ,CRP, and questionnaire are obtained at the start of the study, after two month, and at the end of the study.

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is based on block randomization in blocks of four, This list is built up by an online software available at www.random.org website. Patients were divided in two groups of twenty patients based on blocks of four. One group of twenty patients will receive treatment and the other group will receive placebo. The researcher is not aware about patients allocation.

Blinding (investigator's opinion)
Double blinded

Blinding description
Drug and placebo are filled by a third person in same packs and coding's are included by two numbers and two letters (unique codes assigned for each packs). Researcher is blinded about these codes up to end of the search.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran Islamic Azad University of Medical sciences.

Street address

Yakhchal street, Shariati street,Tehran town.

City

Tehran

Province

Tehran

Postal code

4563490102

Approval date

2020-12-20, 1399/09/30

Ethics committee reference number

IR.IAU.PS.REC.1399.275

Health conditions studied

1

Description of health condition studied

Ulcerative colitis

ICD-10 code

K51.9

ICD-10 code description

Ulcerative colitis, unspecified

Primary outcomes

1

Description

Calprotectin detection by Radio immune assay

Timepoint

Measurement of Calprotectin at the beginning of the study and after 2 months.

Method of measurement

Stool calprotectin measurement by Radio immune assay

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 20 patients of ulcerative colitis who refer to gastrointestinal department of Bouali hospital (Tehran-Iran) will receive atorvastatin 40mg (Sobhan Darou-Rasht-Iran) in similar packs and will take them once daily oral used for 2 months.

Category

Treatment - Drugs

2

Description

Control group: 20 patients of ulcerative colitis who refer to gastrointestinal department of Bouali hospital (Tehran-Iran) will receive placebo tablets that made in Tehran medical science Islamic Azad University in similar packs and will take them once daily oral used for 2 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology clinic of Bu Ali hospital Tehran

Full name of responsible person

Babak Bani Adam

Street address

yakhchal ave, Shariati Srteet, Tehran Town.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farshad Hashemian

Street address

Yakhchal ave., Shariati street., Tehran town

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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

Islamic Azad University

Proportion provided by this source

10

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

Islamic Azad University

Full name of responsible person

Ramin Abrishami

Position

proffessor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Javad Rastegar Moghaddam

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Babak Bani Adam

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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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