

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison the effect of atorvastatin nd placebo on disease flare frequency in patients with ulcerative colitis: a randomized clinical trial

Protocol summary

Summary

Objective: evaluation the effect of atorvastatin in patients with ulcerative colitis. Design of the study: randomization using random permuted blocks, convenience sampling, double-blind, placebo-controlled, single-center, phase II trial. Study population: all patients in the age range of 18 to 60 years old with a definite pathological diagnosis of UC. Main inclusion criteria: developing ulcerative colitis with pathologic confirmation; patients at the age of 18-60 years old. Main exclusion criteria: not taking medication as directed by doctor; drug allergy or severe drug side effects; cancer; history of surgery on the gastrointestinal tract; malabsorption disease; vasculitis disease. Sample size: 20. Interventions: addition of 20 miligram atorvastatin/daily for 6 months to routine treatment regime including asacol, azathioprine and hydrocortisone in intervention group. In control group, patients will receive the same regime except they receive placebo instead of atorvastatin. Intervention time: after the diagnosis. Outcomes of interest: hospitalization rate, the need for steroids, frequency of flare, duration of remission.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102730528N1**

Registration date: **2017-01-01, 1395/10/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-01, 1395/10/12

Registrant information

Name

Leila Hosseini

Name of organization / entity

Zahedan Medical University of Science

Country

Iran (Islamic Republic of)

Phone

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Email address

dr.hosseini@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zahedan University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of atorvastatin nd placebo on disease flare frequency in patients with ulcerative colitis: a randomized clinical trial

Public title

The effect of atorvastatin in the treatment of ulcerative colitis

Purpose

Treatment

Inclusion/Exclusion criteria

Main inclusion criteria: developing ulcerative colitis with pathologic confirmation; patients at the age of 18-60 years old. Main exclusion criteria: not taking medication

as directed by doctor; drug allergy or severe drug side effects; cancer; history of surgery on the gastrointestinal tract; malabsorption disease; vasculitis disease.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization using random permuted blocks

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan Medical University of Science

Street address

Ethics Committee of Zahedan Medical University of Science, Zahedan Medical University of Science, Dr.Hesabi Square, Zahedan

City

Zahedan

Postal code

Approval date

2015-06-10, 1394/03/20

Ethics committee reference number

IR.ZAUMS.REC.1394.222

Health conditions studied

1

Description of health condition studied

Ulcerative Colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description

Duration of remission

Timepoint

Every 3 months since study start

Method of measurement

Day

2

Description

Frequency of flare

Timepoint

Every 3 months since study start

Method of measurement

Number

3

Description

The need for steroids

Timepoint

Every 3 months since study start

Method of measurement

Miligram per kilogram

4

Description

Number of hospitalization

Timepoint

Every 3 months since study start

Method of measurement

Number

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Addition of 20 miligram atorvastatin/daily for 6 months to routine treatment regime including asacol, azathioprine and hydrocortisone

Category

Treatment - Drugs

2

Description

Control group: Addition of 20 miligram placebo/daily for 6 months to routine treatment regime including asacol, azathioprine and hydrocortisone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-ebn Abi Taleb Hospital, Zahedan

Full name of responsible person

Leila Hosseini

Street address

Internal Medicine Department, Zahedan Ali-ebn Abi
Talib Hospital, Salamat Blvd, Dr.Hesabi Sq., Zahedan

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zahedan University of
Medical Sciences

Full name of responsible person

Mohsen Taheri

Street address

Vice chancellor for research, Zahedan University of
Medical Sciences, Zahedan

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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

Vice chancellor for research, Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Leila Hosseini

Position

Internal Medicine Residence

Other areas of specialty/work**Street address**

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Dr. Alireza Bakhshipour

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Associate Professor of Internal Medicine/ Fellowship of
Gastrointestinal Disease

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Fax**Email****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