

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

:Evaluation of the effect of Vitamin A supplementation in severity of acute ulcerativecolitis

Protocol summary

Study aim

The investigation of the vitamin A supplementation on disease activity index (Mayo clinic score) in patients with ulcerative colitis.

Design

Two-arm, parallel design randomized controlled clinical trial including intervention and placebo group, double blind and randomized sample size: 80 patients (40 patients in each group) clinical trial phase: 3 Randomization will be done using a computer-generated randomization charts

Settings and conduct

In the present double blind randomized controlled clinical trial, 80 patients with ulcerative colitis who will be referred to the gastroenterology clinic of Imam Reza Hospital-Tabriz were selected. The patients will be randomly allocated to the treatment group or the placebo group. Randomization was done using a computer-generated randomization charts. The investigator as well as patients were blinded to intervention. The sample size was calculated based 80% power and α value of 0.05, which necessitated 40 cases in each group. The conventional treatments in both groups will be kept stable for at least a month before study entry and was allowed throughout the trial. The patients in the intervention group were supplemented with 25000 IU/day vitamin A (Zahravi Farmaco) and the patients in placebo group were received placebo for two months.

Participants/Inclusion and exclusion criteria

The symptomatic patients with mayo score of 6-12 (who are symptomatic even after treatment with oral and topical 5ASA) and aged 20-45 years old were included in the study. The patients were excluded if they were pregnant or breastfeeding or intended to be pregnant, had other autoimmune disorders, chronic infectious disease, were using vitamin A supplements regularly and smoked.

Intervention groups

Vitamin A group: 25000 IU/day vitamin A (Zahravi Farmaco) placebo group: placebo

Main outcome variables

Disease activity index (measured using mayo clinic score)

General information

Reason for update

Acronym

mayo score

IRCT registration information

IRCT registration number: **IRCT20180520039738N1**

Registration date: **2018-08-12, 1397/05/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-12, 1397/05/21**

Update count: **0**

Registration date

2018-08-12, 1397/05/21

Registrant information

Name

Mohamadreza Rohani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4460 4118

Email address

mohamadreza.rohani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

2018-06-22, 1397/04/01

Actual recruitment end date

2018-10-17, 1397/07/25

Trial completion date

empty

Scientific title

:Evaluation of the effect of Vitamin A supplementation in severity of acute ulcerativecolitis

Public title

Evaluation of the effect of Vitamin A supplementation in severity of acute ulcerativecolitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

symptomatic patients with mayo score of 6-12 (who are symptomatic even after treatment with oral and topical 5ASA) aged 20-65 years old

Exclusion criteria:

being pregnant or breastfeeding or intended to be pregnant had other autoimmune disorders, had chronic infectious disease were using vitamin A supplements regularly smoked

AgeFrom **20 years** old to **65 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **80**Actual sample size reached: **80****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple Randomization was done using a computer-generated randomization charts.

Blinding (investigator's opinion)

Double blinded

Blinding description

vitamin A and placebo were purchased from the same factory and coded by the third person who is not involved in the study. the patients were received the random code by the secretariat who is not involved in the study. the patients with even numbers will receive the capsules from box A and the patients with odd numbers will receive the capsules from box B.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

ethics committee of Tabriz University of Medical Sciences

Street address

Golgasht St. Tabriz University of Medical Sciences, Tabriz-Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2017-11-11, 1396/08/20

Ethics committee reference number

IR.TBZMED.REC

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**

Disease activity index (measured using mayo clinic score)

Timepoint

Before and after 2 month of intervention

Method of measurement

Clinical data

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 25000 IU vitamin A per day for two months

Category

Treatment - Other

2

Description

Control group: placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam reza tabriz hospital

Full name of responsible person

Mohamadreza rohani

Street address

Golgasht street, imam Reza hospital-Tabriz University of medical sciences, Tabriz-Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Zeinab nikniaz

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znikniaz@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mohamadreza rohani

Position

Fellow

Latest degree

Specialist

Other areas of specialty/work

Gastroenterology and hepatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Kurosh masnadi

Position

Asistant proffesor

Latest degree

Subspecialist

Other areas of specialty/work

Gastroenterology and hepatology

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Person responsible for updating data

Contact

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Position

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Latest degree

Specialist

Other areas of specialty/work

gastroenterology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

demographic characteristics: all data after deleting the
name of patients disease activity questionnaire: all data
after deleting the name of patients serum level of
vitamin A: all data after deleting the name of patients

When the data will become available and for how long

4 months after initiation of the study

To whom data/document is available

research vice chancellor of Tabriz University of medical
sciences

Under which criteria data/document could be used

data analysis can be done on all data

From where data/document is obtainable

Liver and gastrointestinal diseases research center,
Tabriz University of medical sciences

What processes are involved for a request to access data/document

sending the request by email to Liver and
gastrointestinal diseases research center, Tabriz
University of medical sciences

Comments