

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of vitamin A supplementation on immune system indices in patients with ulcerative colitis

Protocol summary

Summary

The aim of this clinical trial is to evaluate the effects of vitamin A supplementation on immune indices in patients with ulcerative colitis. In this study, 40 patients with ulcerative colitis who referred to the Sheikh Alryys clinic and meet inclusion and exclusion criteria will be recruited. The patients will receive two injections of vitamin A with two weeks intervals (each time 50000 IU). Food frequency and clinical questionnaires and serum retinol levels, interleukin 4, 10, and 12, acute phase protein CRP, and the number of lymphocytes TCD4 will be measured before and 45 days after beginning of the intervention and will be compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008184105N3**
Registration date: **2010-09-16, 1389/06/25**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-09-16, 1389/06/25

Registrant information

Name

Beit Allah Alipour

Name of organization / entity

Health & Nutrition Faculty

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

alipourb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tabriz University of Medical Sciences, Nutrition Research Center, Faculty of Health and Nutrition, Gastroenterology Research Center, Imam Reza hospital

Expected recruitment start date

2010-04-22, 1389/02/02

Expected recruitment end date

2010-08-06, 1389/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin A supplementation on immune system indices in patients with ulcerative colitis

Public title

Effect of vitamin A supplementation on immune system indices in patients with ulcerative colitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: presence of ulcerative colitis, age range 20 to 45 years, signing consent, receiving similar medications during 6 months prior to the intervention, (a Salazyny drugs: Azathioprine, sulfasalazine) Exclusion criteria: Presence of any autoimmune disease (disease, MS, lupus erythematosus), chronic exposure to any infectious disease, inflammation, diabetes or cancer, consumption of any food supplement such as multivitamin- mineral, vitamin A, zinc and vitamin D and omega-3), use any type of anti-inflammatory drugs such as NSAIDS and immunosuppressives (cyclosporine and ...), pregnancy or intention to become pregnant, any

surgery during six months prior to the study, BMI more than 30

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **43**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences

City

Tabriz

Postal code

Approval date

empty

Ethics committee reference number

8915

Health conditions studied

1

Description of health condition studied

Ulcerative colitis

ICD-10 code

K51.1

ICD-10 code description

Ulcerative (chronic) ileocolitis

2

Description of health condition studied

Ulcerative colitis

ICD-10 code

K51.0

ICD-10 code description

Ulcerative (chronic) enterocolitis

3

Description of health condition studied

Ulcerative colitis

ICD-10 code

K51.2

ICD-10 code description

Ulcerative (chronic) proctitis

4

Description of health condition studied

Ulcerative colitis

ICD-10 code

K51.3

ICD-10 code description

Ulcerative (chronic) rectosigmoiditis

Primary outcomes

1

Description

CD4 lymphocyte count

Timepoint

before & after (day 0 & 45)

Method of measurement

flowcytometry

2

Description

proinflammatory cytokine (IL12)

Timepoint

before & after (day 0 & 45)

Method of measurement

ELISA

3

Description

acute phase protein(hs-CRP)

Timepoint

before & after (day 0 & 45)

Method of measurement

turbidometric

4

Description

anti inflammatory cytokine(IL10 & IL4)

Timepoint

before & after (day 0 & 45)

Method of measurement

ELISA

5

Description

serum retinol
Timepoint
before & after (day 0 & 45)
Method of measurement
HPLC

Secondary outcomes

1

Description
clinical symptoms
Timepoint
before & after (day 0 & 45)
Method of measurement
trouvel witt index

2

Description
food intake habits & dietary intake
Timepoint
before & after (day 0 & 45)
Method of measurement
FFQ & dietary record (3 days)

Intervention groups

1

Description
Vitamin A supplement, as injections, twice (14 days interval), 50000 IU per injection
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Sheykho al Rayys clinic
Full name of responsible person
Dr M.H, Soomi
Street address
Azadi avenue
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Tabriz University of Medical Sciences
Full name of responsible person
Dr ostadrahimi
Street address
Vice chancellor for research of Tabriz University of

Medical Sciences
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Tabriz University of Medical Sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Nutrition research center
Full name of responsible person
Dr Ostadrahimi
Street address
Tabriz University of Medical Sciences
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nutrition research center
Proportion provided by this source
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

3

Sponsor
Name of organization / entity
Gastroentrolgy & Liver Research Center
Full name of responsible person
Dr M.H. Soomi
Street address
Imam reza hospital
City
Tabriz
Grant name
Grant code / Reference number

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

Yes

Title of funding source

Gastroenterology & Liver Research Center

Proportion provided by this source

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Ostadrahimi

Position

Assistant Professor

Other areas of specialty/work

Street address

Health & Nutrition Faculty of Tabriz Medical Science
University

City

Tabriz

Postal code

Phone

+98 41 1335 7581

Fax

Email

ostadrahimi@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Nasim Abedi Manesh

Position

Student

Other areas of specialty/work

Street address

City

Postal code

Phone

+98 41 1380 2161

Fax

Email

an_abedymanesh@yahoo.com

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