

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 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**

Gastroentology & 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  
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ostadrahimi@tbzmed.ac.ir

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**Person responsible for updating data**

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**Full name of responsible person**

Nasim Abedi Manesh

**Position**

Student

**Other areas of specialty/work**

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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*