

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Evaluation of vitamin B6 efficacy in clinical and laboratory manifestation of patients with Ulcerative colitis

#### Protocol summary

##### Summary

Aim: Evaluation of vitamin B6 efficacy in clinical and laboratory manifestation of patients with ulcerative colitis. Study design: randomized, double blind, controlled with placebo, uni-center, phase 2 trial. Inclusion criteria: patients with ulcerative colitis confirmed by clinical diagnosis, pathology, and previous results of colonoscopy; before this, have not used from vitamin B6 and other vitamin B derivatives for ulcerative colitis; patients in any stage and with any intensity are candidate for participating in the study. Exclusion criteria: persons with parkinsonism that use Levodopa, simultaneously (because of interfere with vitamin B6 and Levodopa); patient unwillingness for continue to study. Sample size: intervention group: 30 persons, and control group: 30 persons. Interventions studied: designed in two groups: group 1: patients with ulcerative colitis (n=30) that receive routine treatment with placebo (40 mg/day), and group 2: patients with ulcerative colitis (n=30) that receive routine treatment with vitamin B6 (40 mg/day). Duration of intervention: 6 months. Initial consequences: intensity rate of clinical signs such as number of daily defecation and admission times, the dosage of Mesalazine.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017063034820N1**  
Registration date: **2017-08-29, 1396/06/07**  
Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2017-08-29, 1396/06/07

#### Registrant information

##### Name

Fateme Panahande

##### Name of organization / entity

Ahvaz Jundishapour University of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

-

##### Email address

panahande.f@ajums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Ahvaz Jundishapour University of Medical Sciences

#### Expected recruitment start date

2017-09-06, 1396/06/15

#### Expected recruitment end date

2018-03-06, 1396/12/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation of vitamin B6 efficacy in clinical and laboratory manifestation of patients with Ulcerative colitis

#### Public title

Effect of vitamin B6 on treatment of ulcerative colitis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: patients with ulcerative colitis confirmed by clinical diagnosis, pathology, and previous results of colonoscopy; before this, have not used from vitamin B6 and other vitamin B derivatives for ulcerative

colitis; patients in any stage and with any intensity are candidate for participating in the study. Exclusion criteria: persons with parkinsonism that use Levodopa, simultaneously (because of interfere with vitamin B6 and Levodopa); patient unwillingness for continue to study.

#### **Age**

From **18 years** old

#### **Gender**

Both

#### **Phase**

2

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ahwaz Jundishapour University of Medical Sciences

##### **Street address**

Ahwaz Jundishapour University of Medical Sciences

##### **City**

Ahwaz

##### **Postal code**

#### **Approval date**

2017-03-07, 1395/12/17

#### **Ethics committee reference number**

IR.AJUMS.REC.1395.821

### **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**

daily defecation

#### **Timepoint**

duration of the study

#### **Method of measurement**

times

#### **2**

#### **Description**

admission

#### **Timepoint**

0 & 6th months of the study

#### **Method of measurement**

times

#### **3**

#### **Description**

Mesalazine drug

#### **Timepoint**

0 & 6th months of the study

#### **Method of measurement**

dosage

### **Secondary outcomes**

#### **1**

#### **Description**

ESR

#### **Timepoint**

0 & 6 months of the study

#### **Method of measurement**

Blood test

#### **2**

#### **Description**

CRP

#### **Timepoint**

0 & 6 months of the study

#### **Method of measurement**

Blood test

#### **3**

#### **Description**

plasma homocysteine

#### **Timepoint**

0 & 6 months of the study

#### **Method of measurement**

Blood test

#### **4**

#### **Description**

stool Calprotectin

#### **Timepoint**

0 & 6 months of the study  
**Method of measurement**  
stool exam

## Intervention groups

### 1

#### Description

Control group: patients with ulcerative colitis (number=30) that receive routine treatment with placebo (40 mg/day).

#### Category

Placebo

### 2

#### Description

Intervention group: patients with ulcerative colitis (number=30) that receive routine treatment with vitamin B6 (40 mg/day).

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Khomeini hospital, Ahwaz Jundishapour University of medical sciences

##### Full name of responsible person

Pezhman Alavinejad

##### Street address

##### City

Ahwaz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahwaz Jundishapour University of Medical Sciences

##### Full name of responsible person

Mr. Dianat

##### Street address

Ahwaz Jundishapour University of Medical Sciences

##### City

Ahwaz

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Ahwaz Jundishapour 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

Ahwaz Jundishapour University of Medical Sciences

##### Full name of responsible person

Fateme Panahande

##### Position

Medical student

##### Other areas of specialty/work

##### Street address

Imam Khomeini hospital

##### City

Ahwaz

##### Postal code

##### Phone

+98 916 674 1582

##### Fax

##### Email

Fateme.b.dr@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Ahwaz Jundishapour University of Medical Sciences

##### Full name of responsible person

Pezhman Alavinejad

##### Position

Assistant professor of gastroenterology and hepatology

##### Other areas of specialty/work

##### Street address

No. 16, 16 Street, Kianpars

##### City

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##### Postal code

##### Phone

+98 61 3292 1839

##### Fax

##### Email

Pezhmanalavinejad@gmail.com

##### Web page address

## Person responsible for updating data

#### Contact

##### Name of organization / entity

Ahwaz Jundishapour University of Medical Sciences

##### Full name of responsible person

Seied Ali Mard

##### Position

Physiologist, phd

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

Ahwaz Jundishapour University of Medical Sciences

**City**

Ahwaz

**Postal code****Phone**

+98 61 3292 1839

**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*