

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

Ahwaz

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