

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Efficacy of Vitamin D on serum level of visfatin and vascular endothelial growth factor (VEGF) among Ulcerative Colitis Patients

Protocol summary

Study aim

Efficacy of Vitamin D on serum level of visfatin and vascular endothelial growth factor (VEGF) among ulcerative colitis patients.

Design

Clinical randomized trial, stratified blocked randomization, double blinded, sham controlled clinical trial with a parallel group design of 90 patients

Settings and conduct

In this double-blind clinical trial, 90 patients 18 to 50 years old with ulcerative colitis in remission status and medications cyclosporine Anti-TNF- α and also not eat, volunteers will be recruited. Screening is done through referral to hospital records and contact with patients living in Tehran and inviting them to the project. For blinding, the note paper is numbered zero and one in 4-digit blocks and by a person other than the researcher, each time, a paper is accidentally taken out of the paper, which is injected for a zero placebo site and one for vitamin D.

Participants/Inclusion and exclusion criteria

Inclusion criteria for the study: 1- People with a diagnosis of ulcerative colitis clinical examination to assess the colonoscopic biopsy and course of the disease in the medical record and confirmed by a gastroenterologist and liver that are in a state of Remission. 2- People who volunteer to participate in the study 3- Age between 18 to 50 years 4-BMI of 18.5 to 30 Exclusion criteria: 1- People in relapse status 2-Pregnant and lactating women 3-Anti-TNF- α drugs such as Infliximab 4- History of kidney stones and any diseases of the kidney, liver, cancer 5- Background taking any supplements containing vitamin D during the three months prior to the study 6-Diagnosis doctor to not being able to participate in the study

Intervention groups

Treatment group 45 patients with ulcerative colitis in Remission status, receive Single dose of 300,000 IU of vitamin D and the placebo group (45 patients with ulcerative colitis in Remission status) receive 1 cc of

normal saline.

Main outcome variables

visfatin and vascular endothelial growth factor (VEGF)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131125015536N7**

Registration date: **2018-02-20, 1396/12/01**

Registration timing: **prospective**

Last update: **2018-02-20, 1396/12/01**

Update count: **0**

Registration date

2018-02-20, 1396/12/01

Registrant information

Name

Mohammad Javad Hosseinzadeh

Name of organization / entity

School of Nutritional Sciences and Dietetics, TUMS

Country

Iran (Islamic Republic of)

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+98 21 8899 3059

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Vitamin D on serum levele of visfatin and vascular endothelial growth factor (VEGF) among Ulcerative Colitis Patients

Public title

Efficacy of Vitamin D on serum levele of visfatin and vascular endothelial growth factor (VEGF)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with a diagnosis of ulcerative colitis clinical examination to assess the colonoscopic biopsy and course of the disease in the medical record and confirmed by a gastroenterologist and liver that are in a state of Remission People who volunteer to participate in the study Age between 18 to 50 years old BMI of 18.5 to 30

Exclusion criteria:

People in relapse status Pregnant and lactating women Anti-TNF- α drugs such as Infliximab History of kidney stones and any diseases of the kidney, liver, cancer Background taking any supplements containing vitamin D during the three months prior to the study Diagnosis doctor to not being able to participate in the study

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Ninety persons were randomized manually using Stratified Blocked Randomization method. Strata were based on age (≤ 35 years/ > 35 years) and BMI (≤ 25 / > 25 kg/m²) with blocks of 4.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding, the note paper is numbered zero and one in 4-digit blocks and by a person other than the researcher, each time, a paper is accidentally taken out of the paper, which is injected for a zero placebo site and one for vitamin D.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Sixth Floor-Central Tehran University-Qods St, Keshavarz Blvd, tehran

City

tehran

Province

Tehran

Postal code

1417653761

Approval date

2018-01-28, 1396/11/08

Ethics committee reference number

IR.TUMS.VCR.REC.1396.4365

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**

serume visfatin

Timepoint

Before and after intervention

Method of measurement

ELISA Kit

2**Description**

serume levele of vascular endothelial growth factor (VEGF)

Timepoint

before and after intervention

Method of measurement

ELISA Kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1 mL 300,000 IU Vitamin D3

Category

Treatment - Drugs

2

Description

1 mL normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

shariati hospital

Full name of responsible person

Amrollah Sharifi

Street address

International Campus-tehran university of medical
science-porsina ave-ghods street-keshavarz blv-
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

معاونت تحقیقات و فن آوری دانشگاه

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Sixth Floor-Central University, Qods St, Keshavarz
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Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

mohammadreza emami

Position

MSc Student Nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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professor

Latest degree
Ph.D.

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Patient dissatisfaction

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available