

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Effect of vitamin D on serum levels of Asymmetric dimethylarginine and immune system cytokines, and Cathelicidin gene expression in Ulcerative Colitis patients

Protocol summary

Summary

This project will be done to evaluate the effect of Vitamin D3 on some biological outcomes in Ulcerative Colitis Patients. The outcomes include ADMA, IL-4, IL-20-IL-12, TNF-alpha, INF-gamma, hs-CRP, PTH and 25-OH-vitamin d3 serum levels and LL-37 gene expression.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062318207N1**
Registration date: **2014-12-18, 1393/09/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-18, 1393/09/27

Registrant information

Name

Amrollah Sharifi

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-11-16, 1393/08/25

Expected recruitment end date

2014-12-21, 1393/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin D on serum levels of Asymmetric dimethylarginine and immune system cytokines, and Cathelicidin gene expression in Ulcerative Colitis patients

Public title

Effect of vitamin D on serum levels of Asymmetric dimethylarginine and immune system cytokines, and Cathelicidin gene expression in Ulcerative Colitis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Ulcerative Colitis patients according to examinations, Colonoscopy, biopsy and medical history endorsed by specialized physician; Remission phase (mild and moderate, not active); Voluntary attendance; Age between 18 to 50 years; Body mass index between 18.5 to 30 kg/m2 Exclusion criteria: Relapse phase patients; Pregnant and lactating women; Patients who receive Anti-TNF-alpha drugs like Infliximab and patients who take Cyclosporine; Patints who have received any form of vitamin D 3 months before intervention

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 90

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

Ethics committee of Tehran University of Medical Sciences

Street address

Ghods street, Keshavarz Blvd, Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2014-09-22, 1393/06/31

Ethics committee reference number

9021324004-1

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

Serum level Tumor Necrosis Factor alpha (TNF- α)

Timepoint

Before an 3 months after intervention

Method of measurement

ELISA kit

2

Description

Serum level of Asymmetric dimethylarginine (ADMA)

Timepoint

Before an 3 months after intervention

Method of measurement

ELISA kit

3

Description

Serum level of Interferon gamma (IFN- γ)

Timepoint

Before an 3 months after intervention

Method of measurement

ELISA kit

4

Description

Serum level of Interleukin 4 (IL-4)

Timepoint

Before an 3 months after intervention

Method of measurement

ELISA kit

5

Description

Serum level of Interleukin 10 (IL-10)

Timepoint

Before an 3 months after intervention

Method of measurement

ELISA kit

6

Description

Serum level of Interleukin 12 (IL-12)

Timepoint

Before an 3 months after intervention

Method of measurement

ELISA kit

7

Description

Serum level hs-CRP

Timepoint

Before an 3 months after intervention

Method of measurement

ELISA kit

8

Description

Cathelicidin (LL-37) gene expression

Timepoint

Before an 3 months after intervention

Method of measurement

qRT-PCR

9

Description

Added at 2017-04-15: CD40L (CD154) gene expression (Fold change)

Timepoint

Added at 2017-04-15: 3 months after the intervention

Method of measurement

Added at 2017-04-15: qRT-PCR

Secondary outcomes

1

Description

Serum Total Calcium

Timepoint

Before and 3 months after intervention

Method of measurement

Calcium Arsenazo III Reagent

2

Description

Dietary intake of Energy, Charbohydrate, Protein and Fat

Timepoint

Before and 3 months after intervention

Method of measurement

Three days 24-hour food recall

3

Description

Body Mass Index

Timepoint

Before and 3 months after intervention

Method of measurement

Scale; Stadiometer; calculation

4

Description

Body temperature

Timepoint

Before and 3 months after intervention

Method of measurement

Thermometer

5

Description

Hemoglobin

Timepoint

Before and 3 months after intervention

Method of measurement

Photometric detection of cyanmetahemoglobin

6

Description

Serum Level of 25-Hydroxy Vitamin D3

Timepoint

Before and 3 months after intervention

Method of measurement

Elisa kit

7

Description

Serum level of Parathyroid Hormone (PTH)

Timepoint

Before and 3 months after intervention

Method of measurement

Elisa kit

8

Description

Systolic and diastolic blood pressure

Timepoint

Before and 3 months after intervention

Method of measurement

Sphygmomanometer

9

Description

Beck Depression score

Timepoint

Before and 3 months after intervention

Method of measurement

Beck Depression Inventory

Intervention groups

1

Description

1 ml 300000 Iu vitamin D3 injection

Category

Treatment - Drugs

2

Description

1 ml normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Shariati Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hanieh Rostam-Abadi

Street address

Ghods St, Keshavarz Blvd, Tehran University of Medical Sciences, Vice-chancellor for research

City

Tehran

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

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**

Golestan University of Medical Sciences

Full name of responsible person

Amrollah Sharifi

Position

PhD in Nutritional Sciences (Minor: Epidemiology),
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Person responsible for updating data

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Full name of responsible person

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Position

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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