Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Country

Iran (Islamic Republic of)

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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
Ṡcale; 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-chancelor 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
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Full name of responsible person
Amrollah Sharifi

Position
PhD in Nutritional Sciences (Minor: Epidemiology), Assistant professor at Golestan University of Med

Other areas of specialty/work

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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