Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Study of the effect of vitamin D supplementation on serum vitamin D concentration, quality of life, disease activity index, and some of inflammatory and oxidative factors in patients with ulcerative colitis with vitamin D deficiency

Protocol summary

Study aim

The aim of this study was to evaluate the effects of supplementation with vitamin D on serum vitamin D concentration, quality of life, disease activity index, and some of inflammatory and oxidative factors in patients with Ulcerative colitis with vitamin D deficiency.

Design

In this research, 50 eligible patients referring to Gastroenterology Clinic of Fayaz Bakhsh Hospital were chosen purposefully and were randomly divided into two groups of receiving high dose vitamin D and low dose vitamin D. Group allocation was concealed by assigning a unique code to each participants.

Settings and conduct

In this research, Ulcerative Colitis (UC) patients will be selected from those who are referred to Gastroenterology Clinic of Fayaz Bakhsh Hospital and met the inclusion criteria. Anthropometric characteristics including weight, height, waist circumference (WC) and hip circumference (HC) will be measured and Body Mass Index (BMI) will be calculated for each patient at the baseline and also at the end of the study. Inflammatory Bowel Disease Questionnaire (IBD-Q9) and Simple Clinical Colitis Activity Index Questionnaire (SCCAI-Q) will be completed for each patient and blood samples will be collected after 12-14 hours fasting at the baseline and after the treatment. Plasma samples will be frozen for measuring inflammatory factors. According to their group, patients will receive supplementation for 12 weeks. To investigate patients diet, a 24 hour recall will be completed at the baseline and at the end of treatment. Patients will be asked not to change their diet and physical activity during the study period.

Participants/Inclusion and exclusion criteria

Inclusion criteria: cases with Ulcerative Colitis; active mild to moderate disease severity; no evident of other intestinal diseases or disorders, inflammatory diseases and infectious diseases; no history of taking supplements such as vitamin D, multivitamin-mineral, omega-3, polyphenolic and antioxidants; not taking anti-coagulation drugs such as Heparin and Warfarin or NSAIDs (Nonsteroidal anti-inflammatory drugs), antihistamines and calcium channel antagonists such as Nifedipine within the past month; patients with vitamin D deficiency (less than 30 nano gram per mili liter); Body Mass Index (BMI) more than 18.5 and less than 30 kg/m2; tendency to participate in this research; no change in drug type & dosage during last month. Exclusion criteria: pregnancy or lactation in women or usage of oral contraceptive drugs; drug type and dosage change during intervention; the patient's unwillingness to continue participation in this research .

Intervention groups

Patients will be devided in to two groups, one group will receive high dose of vitamin D (two pearl of 1000 IU vitamin D daily) and other group will receive low dose of vitamin D (one pearl of 1000 IU vitamin D and one pearl of pelacebo daily)

Main outcome variables

At last effect of vitamin D supplementation on serum vitamin D concentration, TNF-α, interlukin 6, hs-CRP, Total AntiOxidative Capacity, Total Oxidative Capacity, quality of life and relapse of the disease will be assessed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100524004010N22**
Registration date: **2018-02-01, 1396/11/12**
Registration timing: **retrospective**

Last update: **2018-02-01, 1396/11/12**
Update count: **0**

Registration date
2018-02-01, 1396/11/12

Registrant information

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Name of organization / entity
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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
National Nutrition and Food Technology Research Institute

Expected recruitment start date
2017-04-19, 1396/01/30

Expected recruitment end date
2018-01-20, 1396/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effect of vitamin D supplementation on serum vitamin D concentration, quality of life, disease activity index, and some of inflammatory and oxidative factors in patients with ulcerative colitis with vitamin D deficiency

Public title
The effect of vitamin D supplementation in patients with ulcerative colitis

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Cases with Ulcerative colitis Active mild to moderate disease severity No evident affliction with other intestinal diseases or disorders, inflammatory diseases and infectious diseases No history of taking supplements such as vitamin D multivitamin-mineral, omega-3, polyphenolic and antioxidants Not taking anti-coagulation drugs such as Heparin and Warfarin or NSAIDs (Non steroidal anti-inflammatory drugs), antihistamines and calcium channel antagonists such as Nifedipine within the past month Patients with vitamin d defficiency (less than 30 nano gram per mili liter) Body mass index (BMI) over than 18.5 and less than 30 kg/m2 Tendency to participate in this research No change in type & dose of drug usage during last month

Exclusion criteria:
Pregnancy or lactation in women or use of oral contraceptive drugs The patient Unwillingness to continue participation in this research Drug type and dosage change during intervention

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
In this research patients will be gathered by Convenience Sampling and they will be divided in to two groups by Blocked Randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
To make this research double blind, before starting the study a person out of study coded the drug boxes to A, B and C. Box A and B contain vitamin D pearls with the dose of 1000 IU and box C contains pelacebo pearls. All patients receive box A but according to which group they take place, high or low dose vitamin D supplement will receive box B or C respectively. Thus patients in high dose supplementation group receive box A and B and will use one pearl from box A and one from box B daily which provide 2000 IU vitamin D per day. While patients in low dose vitamin D group receive box A and c, will use one pearl from box A and one from box C which provide 1000 IU vitamin d daily.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address
West Arghavan Street, farahzadi Bulevard, Shahrak Qods

City
Tehran
Province
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Postal code
1981619573
Approval date
2017-03-06, 1395/12/16
Ethics committee reference number
IR.SBMU.nnftri.13950110

2

Ethics committee
Name of ethics committee
Ethics Committee of National Nutrition and Food Technology Research Institute
Street address
No 7, West Hafezi Street, Farahzadi Boulevard, Shakrak Gharb
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Province
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Postal code
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Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
IR.SBMU.nnftri.13950110

Health conditions studied

1

Description of health condition studied
ulcerative colitis
ICD-10 code
K51.9
ICD-10 code description
Ulcerative colitis, unspecified

Primary outcomes

1

Description
Simple Clinical Colitis Activity Index
Timepoint
At the beginning and at the end of the study
Method of measurement
Simple Clinical Colitis Activity Index Questionnaire (SCCAIQ)

2

Description
Quality of life
Timepoint
At the beginning and at the end of the study
Method of measurement
Inflammatory Bowel Disease Questionnaire -9 (IBDQ-9)

3

Description
TNF-α
Timepoint
At the beginning and at the end of the study
Method of measurement
ELISA

4

Description
hs-CRP
Timepoint
At the beginning and at the end of the study
Method of measurement
ELISA

5

Description
serum TOC
Timepoint
At the beginning and at the end of the study
Method of measurement
kit

6

Description
serum TAC
Timepoint
At the beginning and at the end of the study
Method of measurement
kit

Secondary outcomes

1

Description
Carbohydrate intake
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

2

Description
Weight
Timepoint
At the beginning and at the end of the study
Method of measurement
Scale

3

Description
Waist circumference
Timepoint
At the beginning and at the end of the study
Method of measurement

Metre

4

Description
Hip circumference
Timepoint
At the beginning and at the end of the study
Method of measurement
Metre

5

Description
Body Mass Index
Timepoint
At the beginning and at the end of the study
Method of measurement
Calculating

6

Description
Total energy intake
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

7

Description
Protein intake
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

8

Description
Total fat intake
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

9

Description
PUFA fatty acid intake (omega 3)
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

10

Description
Cholesterol intake
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

11

Description
Fiber intake
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

12

Description
SFA fatty acid intake
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

13

Description
MUFA fatty acid intake
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

14

Description
PUFA fatty acid intake (omega 6)
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

15

Description
Vitamin E intake
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

16

Description
VitaminC intake
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

17

Description
Zinc intake
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

18

Description
Selenium intake
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

19

Description
Folate intake
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

20

Description
Carotenoids intake
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

21

Description
Vitamin A intake
Timepoint
At the beginning and at the end of the study
Method of measurement
24h recall questionnaire

Intervention groups

1

Description
vitamin D supplement for 12 weeks 2 pearl contain 1000 IU daily
Category
Treatment - Drugs

2

Description
One vitamin D supplement 1000 IU daily and one pelacebo for 12 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fayaz Bakhsh Hospital
Full name of responsible person
Azita Hekmat doost
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Sponsors / Funding sources

1

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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti Nutrition Faculty
Full name of responsible person
Azita Hekmatdoost
Position
Associate Professor

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available