Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of Gluten Free Diet on TNF-α and Iron Deficiency Anemia in Ulcerative Colitis

Protocol summary

Summary

Objectives:The objective of this study Is to evaluate the effect of Gluten Free Diet on serum Tumor Necrosis Factor-alpha (TNF-α) and Iron Deficiency Anemia in patients diagnosed with Ulcerative Colitis. Design: Non-random allocation to intervention or control groups, Not blinded and without placebo, Single-center, Phase 3 trials. Setting and conduct: 1.Sample size, time and patients: 56 patients in two groups with mild and severe Ulcerative Colitis without Celiac disease will be chosen from Inflammatory Bowel Disease center of Imam Reza Hospital of Tabriz from January to February. 2.Intervention: After one month of wash out period in which patients will have their routine diets, Gluten Free Diet for one month will be given to them and TNF-α and anemia factors at three phases of baseline, beginning of intervention and end of intervention will be studied. Then results will be analyzed. 3. The main inclusion and exclusion criterias: Exclusive Inclusion criteria is inactive ulcerative colitis. Having a history of consuming Gluten Free Diet, using Aspirin or Nonsteroidal Anti-Inflammatory Drugs in the last few weeks of study, smoking or using drugs in the last 6 weeks and having Celiac disease alongside UC are exclusion criterias. 4. The main variables: TNF-α, Hemoglobin, Hematocrit, Red Blood Cells, serum Ferritin, serum Iron and TIBC are the main variables that will be examined in this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062113678N4**
Registration date: **2016-08-25, 1395/06/04**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-08-25, 1395/06/04

Registrant information

Name
Saeed Ghavamzadeh
Name of organization / entity
Urmia University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Urumia University Of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-03-05, 1395/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Gluten Free Diet on TNF-α and Iron Deficiency Anemia in Ulcerative Colitis

Public title

The effect of Gluten Free Diet on Ulcerative Colitis

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: being diagnosed with either mild or severe Ulcerative Colitis according to Up To Date 21-2

standard who are not in remission exclusion criteria: having a history of consuming Gluten Free Diet, using Aspirin or nonsteroidal anti-inflammatory drugs in the last few weeks of study, smoking or using drugs in the last 6 weeks and having celiac disease alongside UC (based on medical file or patient’s statements)

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Research And Technology Center,3rd floor,Central building,Golgasht street, Tabriz

City
Tabriz

Postal code

Approval date
2014-11-24, 1393/09/03

Ethics committee reference number
93127

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
Mean Corpuscular Hemoglobin Concentration (MCHC)

Timepoint
entering to the study,end of the washout period, end of the study

Method of measurement
ELISA

2

Description
Hemoglubolin

Timepoint
entering to the study,end of the washout period, end of the study

Method of measurement
ELISA

3

Description
Hematocrit

Timepoint
entering to the study,end of the washout period, end of the study

Method of measurement
ELISA

4

Description
Red Blood Cells

Timepoint
entering to the study,end of the washout period, end of the study

Method of measurement
ELISA

5

Description
Ferritin

Timepoint
entering to the study,end of the washout period, end of the study

Method of measurement
ELISA

6

Description
Serum Iron

Timepoint
entering to the study,end of the washout period, end of the study

Method of measurement
ELISA

7

Description
Total Iron-Binding Capacity (TIBC)
Timepoint
entering to the study,end of the washout period, end of the study
Method of measurement
ELISA

8

Description
Mean Corpuscular Volume (MCV)
Timepoint
entering to the study,end of the washout period, end of the study
Method of measurement
ELISA

9

Description
Mean Corpuscular Hemoglobin (MCH)
Timepoint
entering to the study,end of the washout period, end of the study
Method of measurement
ELISA

10

Description
Red Cell size distribution Width (RDW)
Timepoint
entering to the study,end of the washout period, end of the study
Method of measurement
ELISA

Secondary outcomes

1

Description
Anti-tissue Transglutaminase IgA antibodies (tTGA)
Timepoint
entering to the study,end of the washout period, end of the study
Method of measurement
ELISA

2

Description
White Blood Cell (WBC)
Timepoint
entering to the study,end of the washout period, end of the study
Method of measurement
ELISA

3

Description
Platelet
Timepoint
entering to the study,end of the washout period, end of the study
Method of measurement
ELISA

4

Description
Tumor Necrosis Factor alpha (TNF-alpha)
Timepoint
entering to the study,end of the washout period, end of the study
Method of measurement
ELISA

Intervention groups

1

Description
training gluten free diet for one month
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Inflammatory Bowel Disease Center
Full name of responsible person
Dr Masnadi Shirazi Koorosh
Street address
1st floor, Emam Reza hospital, Golgasht, Tabriz, East Azarbayjan, Iran
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research Urumia University of Medical Sciences
Full name of responsible person
Dr Mohebbi Iraj
Street address
Research and Technology Center of Urumia Medical Science Univercity
City
Urumia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Vice Chancellor for research Urumia 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Urumia Univercity of Medical Science
Full name of responsible person
Dr Saeed Ghavamzadeh
Position
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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