Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effects of Taurine on clinical symptoms and laboratory parameters of ulcerative colitis patients.

Protocol summary

Summary

The aim of present study was to examine the effects of Taurine on clinical signs/symptoms and laboratory tests of ulcerative colitis patients. The study is a randomized and will be performed in a single center. Patients of both sexes (18 to 60 year old) who are newly diagnosed with ulcerative colitis and are in their first month of therapy or those who are not controlled with existing therapies will be invited to the study. Diagnosis and expansion of disease will be determined according to clinical symptoms and endoscopic examination. Exclusion criteria will be pregnant women; presence of disease for less than 2 weeks; crohn's disease patients; patients who receive supplements; patients with systemic disease (tumor or perforation), other inflammatory disease or history of surgery. 100 patients will be selected randomly and will be divided into two groups using Random Allocation software. 50 of these patients will receive 1g/day Taurine capsules for 8 weeks in addition to their routine treatment (Intervention group). Other 50 patients will receive routine treatment (Control group). Patients clinical signs/symptoms and quality of life will be recorded in a questionnaire. Laboratory parameters of CBC, ESR,CRP and measurement of Cytokines (TNF-alfa, IL1b and IL6) and taurine concentration in serum will be measured using available methods. These factors will be compared between two groups at the beginning of the study and after 8 weeks of starting the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101275704N1**
Registration date: **2011-04-26, 1390/02/06**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-04-26, 1390/02/06

Registrant information

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Simin Ozar Mashayekhi
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Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences (Liver and Gastrointestinal disease research center)

Expected recruitment start date

2011-05-05, 1390/02/15

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Taurine on clinical symptoms and laboratory parameters of ulcerative colitis patients.

Public title

Effects of Taurine on treatment process of ulcerative colitis patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients of both sex, who are recently diagnosed with ulcerative colitis and are being treated for a maximum of 1 month; or their disease is not controlled by routine treatments. Exclusion criteria:pregnant women; presence of signs and symptoms for less than 2 weeks; diagnosed with crohn's disease; patients who receive supplements; patients with systemic disease such as tumor or perforation; patients with other inflammatory disease or history of surgery

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

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

Vice Chancellor of Tabriz University of Medical Science, 2nd main Building, Daneshgah St.

City

Tabriz

Postal code

5166414766

Approval date

2011-04-18, 1390/01/29

Ethics committee reference number

746/4/5

Health conditions studied

1

Description of health condition studied

ulcerative colitis

ICD-10 code

K-51

ICD-10 code description

Ulcerative colitis

Primary outcomes

1

Description

Disease signs and symptoms

Timepoint

Prior to intervention and 8 weeks after intervention

Method of measurement

Standard questionaire

Secondary outcomes

1

Description

TNF-α (tumour necrosis factor α) serum concentration

Timepoint

Prior to intervention and 8 weeks after intervention

Method of measurement

ELISA

2

Description

interleukin (IL)-6 serum concentration

Timepoint

Prior to intervention and 8 weeks after intervention

Method of measurement

ELISA

3

Description

C-Reactive Protein

Timepoint

Prior to intervention and 8 weeks after intervention

Method of measurement

Available and tested methods

4

Description

erythrocyte sedimentation rate (ESR)

Timepoint

Prior to intervention and 8 weeks after intervention

Method of measurement

Available and tested methods

5

Description

interleukin (IL)-1b serum concentration

Timepoint

Prior to intervention and 8 weeks after intervention

Method of measurement

ELISA

6

Description

taurine concentration in serum

Timepoint

Prior to intervention and 8 weeks after intervention

Method of measurement

HPLC

7

Description

Serum Albumin concentration

Timepoint

Prior to intervention and 8 weeks after intervention

Method of measurement

Available and tested methods

8

Description

Quality of life

Timepoint

Prior to intervention and 8 weeks after intervention

Method of measurement

Questionaire

Intervention groups

1

Description

The intervention group will receive 1 g taurine every day for 8 weeks in addition to their routine treatment and the mentioned outcome will be evaluated at time zero and 8 weeks later. Taurine is an amino acid which is commonly found in sea foods and energy drinks. Each of our patients will receive 1 g taurine (as capsule) each day for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group will receive routine treatment and the mentioned outcomes will be evaluated at time zero and 8 weeks later.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheykh-o-alrais medical center

Full name of responsible person

Niko Seraji; paria Habiballahi

Street address

Azadi St, between Jodeyri and Gholgasht St

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tabriz University of Medical Sciences (Liver and Gastrointestinal di

Full name of responsible person

Dr Mohammadreza Rashidi

Street address

Vice Chancellor for research of Tabriz University of Medical Science, 2nd main Building, Daneshgah St.

City

Tabriz

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 of Tabriz University of Medical Sciences (Liver and Gastrointestinal di

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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Simin Mashayekhi

Position

PhD, Assistant professor

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