

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation of the effects of Resveratrol on serum TNF- α and hs-CRP and quality of life in patients with ulcerative colitis.

Protocol summary

Summary

To study the effects of resveratrol supplement on serum TNF- α and hs-CRP and quality of life in patients with ulcerative colitis. 50 patients who referred to Gastrointestinal (GI) clinic with mild-moderate active ulcerative colitis will be randomly allocated to receive either 500 mg resveratrol or placebo for 6 weeks. At the first and the end of the intervention, serum TNF- α and hs-CRP and quality of life will be assessed and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209154010N10**
Registration date: **2013-01-31, 1391/11/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-31, 1391/11/12

Registrant information

Name

Azita Hekmatdoost

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Technology Research Institute (NNFTRI) and Digestive Disease Research Institute (DDRI)

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2013-03-21, 1392/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of Resveratrol on serum TNF- α and hs-CRP and quality of life in patients with ulcerative colitis.

Public title

Evaluation of the effects of Resveratrol on serum TNF- α and hs-CRP and quality of life in patients with ulcerative colitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 years and older; BMI between 18.5-30; histopathologic findings compatible with ulcerative colitis (mild-moderate active). Exclusion criteria: other enteral, autoimmune, inflammatory diseases and cancers; Pregnancy & Breast feeding, use of oral contraceptive drugs, using multivitamins, minerals, omega-3, poly phenolic and anti oxidant supplements in previous month, Use of drugs such as calcium channel blockers, NSAIDs, heparin, varfarin and anti histamin in previous month; changes in dosage and kind of drugs in previous month and changes in dosage and kind of drugs during intervention; activation of disease resulting to hospitalization; reluctance to

continue.

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

National Nutrition and Food Technology Research
Institute (NNFTRI)

Street address

West Arghavan, Shahrak Ghods

City

Tehran

Postal code

Approval date

2012-08-20, 1391/05/30

Ethics committee reference number

046467

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

quality of life (IBDQ-9)

Timepoint

at weeks: 0 and 6

Method of measurement

questionnaire

2

Description

serum TNF-a

Timepoint

at weeks: 0 and 6

Method of measurement

ELISA

3

Description

serum hs-CRP

Timepoint

at weeks: 0 and 6

Method of measurement

ELISA

Secondary outcomes

1

Description

weight and BMI

Timepoint

at weeks: 0 and 6

Method of measurement

Weight will be measured by Secca scale , BMI by formula

2

Description

waist circumference, hip circumference

Timepoint

at weeks: 0 and 6

Method of measurement

non stretch meter

3

Description

height

Timepoint

at weeks: 0 and 6

Method of measurement

non stretch meter

Intervention groups

1

Description

control group: placebo

Category

Placebo

2

Description

Intervention group: 500 mg/day resveratrol

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Nutrition and Food Technology Research
Institute (NNFTRI)

Full name of responsible person

Dr. Hosseini

Street address

West Arghavan, Shahrak Ghods

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

National Nutrition and Food Technology Research
Institute (NNFTRI)

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

National Nutrition and Food Technology Research
Institute (NNFTRI)

Full name of responsible person

Azita Hekmatdoost, MD, PhD

Position

Assistant Prof.

Other areas of specialty/work

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Person responsible for updating data

Contact

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