Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effects of Resveratrol on serum TNF-α and hs-CRPand 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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Country

Iran (Islamic Republic of)

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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-CRPand quality of life in patients with ulcerative colitis.

Public title

Evaluation of the effects of Resveratrol on serum TNF-α and hs-CRPand 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; reluctancy 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
questionnarie

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 circumfereance

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
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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