Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

The effect of resveratrol on children and adolescents with inflammatory bowel disease (IBD)

Protocol summary

Study aim
Determination of resveratrol effect on inflammatory bowel disease activity indices, inflammatory factors, antioxidants and anthropometry in children and adolescents with inflammatory bowel disease (IBD)

Design
This study is a double-blind study with a control group with parallel randomized groups and is performed on 70 patients in phase 3.

Settings and conduct
This study will be performed on 70 children and adolescents aged 8-18 years in the Children's Medical Center Hospital. The study will be conducted in double-blind with the control group. The intervention group will receive 150 mg of resveratrol per day and the control group will receive 150 mg of placebo per day for 12 weeks. At the beginning and after 12 weeks, the different effects of the intervention on these people are examined and compared.

Participants/Inclusion and exclusion criteria
. Girls and boys aged 8 to 18 years . Diagnosis of IBD based on endoscopic, laboratory studies, and clinical examinations . Absences other diseases and chronic and acute liver disorders (hepatitis B, C, etc.), biliary disease, other gastrointestinal diseases, chronic diseases (including type one or two diabetes, cardiovascular, pulmonary and celiac disease), autoimmune diseases Known and inherited and metabolic disorders. . No pregnancy or breastfeeding in women . No substance abuse, no chronic inflammatory disease, no history of cancer, no hormone therapy, no recent weight loss diet. . No history of gastrointestinal surgery.

Intervention groups
Study doses of resveratrol vary from 75 mg daily to 5 g once daily, twice or thrice daily.

Main outcome variables
Disease activity index-Weight-Body mass index-Serum level of inflammatory factors-Serum albumin, and calcium levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220409054467N1**
Registration date: **2022-04-27, 1401/02/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-27, 1401/02/07**
Update count: **0**

Registration date
2022-04-27, 1401/02/07

Registrant information
Name
Pejman Rohani
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 6694 1417
Email address
rohanipejmanmd@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-21, 1401/02/01

Expected recruitment end date
2023-04-21, 1402/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of resveratrol on children and adolescents with inflammatory bowel disease (IBD)

Public title

The effect of resveratrol on children and adolescents with inflammatory bowel disease (IBD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to cooperate and sign the informed consent form after full knowledge of the objectives and methods of the study. Girls and boys aged 8 to 18 years. Diagnosis of IBD based on endoscopic, laboratory studies, and clinical examinations. Absences other diseases and chronic and acute liver disorders (hepatitis B, C, etc.), biliary disease, other gastrointestinal diseases, chronic diseases (including type one or two diabetes, cardiovascular, pulmonary and celiac disease), autoimmune diseases Known and inherited and metabolic disorders. No history of alcohol consumption or alcohol consumption more than 10 grams per day in women and more than 20 grams per day in men. No pregnancy or breastfeeding in women. No substance abuse, no chronic inflammatory disease, no history of cancer, no hormone therapy, no recent weight loss diet. No history of gastrointestinal surgery. Do not take medications or supplements that affect appetite, weight, or metabolism for at least 6 months before the study (such as medications that affect carbohydrate, protein, or fat metabolism, and medications that reduce or increase appetite or food intake, including herbal supplements).

Exclusion criteria:

Having any acute illness The occurrence of any accident that affects a person's health. Use of antibiotics during the study Acceptance rate less than 80% Immigration Exclusion based on personal preference of participants or their parents Changes in medications taken during the study period

Age

From **8 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be used as Stratified Randomization using the Permuted block randomization method with quadruple and double blocks. According to the sample size of 70 that has been determined, the quadruple and double blocks will be produced using the online site (www.sealedenvelope.com).In the Stratified Randomization method, age and BMI will be used as layers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study is double-blind. Participants will be divided into two groups receiving resveratrol supplementation and the placebo group. Due to the double-blindness of the study, before starting the study, sets of cans containing resveratrol supplementation will be prepared by someone other than the researcher, and the placebo will be similar in appearance to resveratrol, so that the researcher does not know the type of treatment received by each group. In addition, the researcher in the evaluation phase of the desired outcomes (anthropometric measurements, blood tests, biochemistry and severity of inflammatory bowel disease) from the allocation of participants in each of the groups (intervention and control group) until after the end of the intervention period will be uninformed.

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Children’s Medical Center- Tehran University of Medical Sciences

Street address

Children's Medical Center, Dr Gharib St, Keshavarz Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733151

Approval date

2022-04-04, 1401/01/15

Ethics committee reference number

IR.TUMS.CHMC.REC.1401.014

Health conditions studied

1

Description of health condition studied

Inflammatory bowel disease

ICD-10 code

K51.412

ICD-10 code description

Inflammatory polyps of colon with intestinal obstruction

Primary outcomes

1

Description
Disease activity index
Timepoint
Beginning and end of the study
Method of measurement
Software for calculating pediatric Crohn's disease activity index (PCDAI) and pediatric ulcerative colitis activity index (PUCAI)

2

Description
Serum C-reactive protein (CRP) levels
Timepoint
Beginning and end of the study
Method of measurement
Laboratory kit

3

Description
Serum tumor necrosis factor (TNF) levels
Timepoint
Beginning and end of the study
Method of measurement
Laboratory kit

4

Description
Serum total antioxidant capacity (TAC) levels
Timepoint
Beginning and end of the study
Method of measurement
Laboratory kit

5

Description
Serum malondialdehyde (MDA) levels
Timepoint
Beginning and end of the study
Method of measurement
Laboratory kit

Secondary outcomes

1

Description
Weight
Timepoint
Beginning and end of the study
Method of measurement
scale

2

Description
Body mass index
Timepoint
Beginning and end of the study
Method of measurement
Calculation

3

Description
Serum Albumin
Timepoint
Beginning and end of the study
Method of measurement
Laboratory kit

Intervention groups

1

Description
Intervention group: The intervention group receiving resveratrol supplements will receive two 75 mg supplements daily for 12 weeks due to the better effectiveness of this supplement at lower doses and the lack of side effects reported at low doses. These supplements are provided by Karen Pharmaceuticals and Vital-Food Supplements Company.
Category
Treatment - Drugs

2

Description
Control group: Control group will receive two maltodextrin supplements daily for 12 weeks. These supplements are provided by Karen Pharmaceuticals and Vital-Food Supplements Company.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Children's Medical Center
Full name of responsible person
Pejman Rohani
Street address
Children's Medical Center, Dr Gharib St, Keshavarz Blvd, Tehran, Iran
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cmcpr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotouhi, Deputy head for Research and Technology, Tehran University of Medical Sciences.
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Tehran University of Medical Sciences, Keshavarz Blvd, Tehran, Iran
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Email
vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Pejman Rohani
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
There is no more information
When the data will become available and for how long
There is no more information
To whom data/document is available
Responsible researchers in the university and the journal related to the article
Under which criteria data/document could be used
At the request of the authorities and the relevant journals after reviewing the reason for publication by the responsible author
From where data/document is obtainable
Pediatric Medical Center, Pediatric Gastroenterology and Liver Research Center.
What processes are involved for a request to access data/document
There is no more information
Comments