

# 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)

##### Phone

+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

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733151

##### Phone

+98 21 6693 0024

##### Email

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.

**Street address**

Tehran University of Medical Sciences, Keshavarz Blvd, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733151

**Phone**

+98 21 6693 0024

**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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733151

**Phone**

+98 21 6693 0024

**Email**

cmcpr@tums.ac.ir

## Person responsible for scientific 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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733151

**Phone**

+98 21 6693 0024

**Email**

cmcpr@tums.ac.ir

## Person responsible for updating data

**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

**Street address**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733151

**Phone**

+98 21 6693 0024

**Email**

cmcpr@tums.ac.ir

## 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