Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Effects of Adalimumab in Iranian Pediatric with Inflammatory Bowel Disease

Protocol summary

Study aim
Determining the efficacy and side effects of adalimumab in children aged 2-18 years with inflammatory bowel disease

Design
This study is conducted as a single-group clinical trial in phase 3 on 25 patients.

Settings and conduct
This study will be conducted on 25 children and adolescents aged 2-18 years. The study will be conducted as a single-group clinical trial with the administration of adalimumab as the intervention group. At the beginning and after 4 and 26 weeks, the different effects of the intervention are examined and compared.

Participants/Inclusion and exclusion criteria
Girls and boys aged 2 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. presence of perianal fistula. active disease despite administration of corticosteroids.

Intervention groups
Administration of adalimumab (40 mg/0.8 ml) which is injected in patients weighing less than 40 kg based on the following dose: 80 mg first, 40 mg two weeks later, 20 mg two weeks after the second dose and then depending on the response, 20 mg should be taken subcutaneously once every one or two weeks. Also, subcutaneous injection was performed for people weighing more than 40 kg based on the following dose: first 160 mg, two weeks later 80 mg, two weeks after the second dose 40 mg, then according to the response, 40 mg is injected every one or two weeks.

Main outcome variables
Clinical activity score, weight, fecal calprotectin.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220409054467N3**
Registration date: **2022-08-15, 1401/05/24**
Registration timing: **prospective**

Last update: **2022-08-15, 1401/05/24**
Update count: **0**

Registration date
2022-08-15, 1401/05/24

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
2022-08-23, 1401/06/01

Expected recruitment end date
2023-03-21, 1402/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Adalimumab in Iranian Pediatric with Inflammatory Bowel Disease

Public title
Effects of Adalimumab in Iranian Pediatric with Inflammatory Bowel Disease

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 2 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. Presence of perianal fistula. Active disease despite the administration of corticosteroids Failure to respond to immunomodulators

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 **2 years** old to **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **25**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

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
2022-05-31, 1401/03/10

Ethics committee reference number
IR.TUMS.CHMC.REC.1401.061

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
Fecal calprotectin level

Timepoint
Beginning and end of the study

Method of measurement
Laboratory kit

3

Description

Weight

Timepoint

Beginning and end of the study

Method of measurement

scale

Secondary outcomes

1

Description

Serum C-reactive protein (CRP) levels

Timepoint

Beginning and end of the study

Method of measurement

Laboratory kit

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: Administration of adalimumab (40 mg/0.8 ml) which is injected in patients weighing less than 40 kg based on the following dose: 80 mg first, 40 mg two weeks later, 20 mg two weeks after the second dose and then depending on the response, 20 mg should be taken subcutaneously once every one or two weeks. Also, subcutaneous injection was performed for people weighing more than 40 kg based on the following dose: first 160 mg, two weeks later 80 mg, two weeks after the second dose 40 mg, then according to the response, 40 mg is injected every one or two weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children's Medical Center

Full name of responsible person

Pejman Rohani

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

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Email

cmcpr@tums.ac.ir

Web page address

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

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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 scientific inquiries

Contact

Name of organization / entity
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Person responsible for updating data

Contact

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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
-

When the data will become available and for how long
-

To whom data/document is available
-

Under which criteria data/document could be used
-

From where data/document is obtainable
-

What processes are involved for a request to access data/document
-

Comments
-