

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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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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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
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Pejman Rohani
Position
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Latest degree
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

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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

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