

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

A phase 3, randomized, multicenter, double-blind, two-armed, parallel, active-controlled, Non-inferiority clinical trial to compare efficacy and safety of Infliximab (Infliximab produced by AryoGen Pharmed co) versus Remicade® (Infliximab produced by Janssen Immunology co.) in patients with active moderate to severe Ulcerative Colitis

Protocol summary

Study aim

Assessment of the non-inferiority of Infliximab (AryoGen) to Remicade (Janssen) in terms of efficacy in moderate to severe active UC

Design

phase III, randomized, two-armed, double-blind, parallel, active-controlled, non-inferiority clinical trial

Settings and conduct

260 Ulcerative colitis patients in multiple centers (Tehran, Shiraz, Mashhad, Isfahan, Sari, Rasht and Bandar-abbas), randomized, double-blind (patient, health-care provider and analyzer)

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 to 65 years, moderate to severe active UC with indication for Infliximab therapy, ICF signing
Exclusion criteria: Diagnosis of acute severe UC, Proctitis, indeterminate colitis, crohn's disease, colonic obstruction, colonic mucosal dysplasia, adenomatous colonic polyps, TB, hepatitis B/C, HIV, history of toxic megacolon, C.diff, CMV within 30 days, herpes zoster, other autoimmune diseases, moderate to severe HF, active infection, history of severe fixed symptomatic stenosis, malignancy, demyelinating diseases, pregnancy or breast feeding, hypersensitivity, receiving protocol-prohibited treatments, abnormal lab tests, vaccinations, recent treatment with investigational agent, other conditions making subject enrollment inappropriate

Intervention groups

Intervention: Infliximab (AryoGen) 5 mg/kg, IV infusion, at day 0 and weeks 2, 6, 14, and 22
Control: Remicade (Janssen) 5 mg/kg, IV infusion, at day 0 and weeks 2, 6, 14, and 22

Main outcome variables

Percentage of patients achieving clinical response at

week 8

General information

Reason for update

Minor changes were made to numbers 6, 15, 17, and 22 in the "Exclusion Criteria" section. In section 6, "ozanimod" was added. In section 15, the word "history" was added to toxic megacolon. Section 17 was changed to "CMV within the past 30 days" and in section 22, the word "severe" was removed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20150303021315N36**

Registration date: **2025-03-21, 1404/01/01**

Registration timing: **prospective**

Last update: **2026-02-02, 1404/11/13**

Update count: **3**

Registration date

2025-03-21, 1404/01/01

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-05-28, 1404/03/07

Expected recruitment end date

2027-07-31, 1406/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A phase 3, randomized, multicenter, double-blind, two-armed, parallel, active-controlled, Non-inferiority clinical trial to compare efficacy and safety of Infliximab (Infliximab produced by AryoGen Pharmed co) versus Remicade® (Infliximab produced by Janssen Immunology co.) in patients with active moderate to severe Ulcerative Colitis

Public title

Evaluation of non-inferiority of efficacy and safety of Infliximab (AryoGen) VS Remicade (Janssen) in UC

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-65 years Moderate to severe active UC ICF signing

Exclusion criteria:

Active/latent TB serious allergies to the formulation Hepatitis B/C or HIV Recent gastrointestinal surgery indeterminate colitis or Crohn Receiving biologics, JAK inhibitors or ozanimod Tacrolimus and Cyclosporine within 4weeks Proctitis ASUC that requires hospitalization Severe fixed symptomatic stenosis of intestine Colonic obstruction or history of that within 6months Having or history of colonic mucosal dysplasia Adenomatous colonic polyps Malignancy within 5years History of Toxic megacolon C.diff within 60days CMV within 30days Receiving IV corticosteroids within 14days Herpes zoster within 8 weeks History of demyelinating diseases Diagnosis of other autoimmune-diseases HF class III/IV Abnormalities in laboratory data Receiving live/attenuated vaccine less than 4weeks or planning to receive them Pregnancy/ breastfeeding or planning to pregnancy in study Active infection or history of hospitalization or receiving IV antibiotics within 8weeks or oral within 2weeks Other disease or disorder which put the subject at risk Treatment with any investigational agent in the past 4 weeks or passing less than five half-lives of agent

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **260**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization plan of the patients will be carried out centrally using an R-CRAN software version 4.2.1. Blocks (with the size 2 or 4) will be made using permuted block randomization for a total of 260 patients (1:1 allocation ratio). After the randomization procedure, a code will be allocated to each patient that will be used as a patient identifier throughout the study. The assigned code will be denoted by 4 initials (corresponding to the first two letters of the first name, the first two letters of the surname) and three numbers (center code). Moreover, the described code is followed by a study unique identification code consisting of the first three letters of the generic name of the investigational product, respectively (IFX), and three numbers (corresponding to the randomization number), e.g., ABCD001IFX-001. The randomization number will be assigned in a consecutive way.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, subjects and the product administrators are blinded. The size of vials is different. For this purpose, subjects and administrator of the drug will be blinded by considering two nurses in each center: one nurse who opens the drug package and prepares the drug for injection, and another nurse who injects the drugs and will remain blind throughout the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

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Approval date

2025-02-19, 1403/12/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1403.612

Health conditions studied**1****Description of health condition studied**

Ulcerative Colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes**1****Description**

Percentage of patients achieving clinical response based on MAYO score at week 8Clinical response: At least 3 points and 30% decrease from screening in the total MAYO Score; Decrease in the subscore for rectal bleeding of at least 1 point or an absolute subscore for rectal bleeding of 0 or 1.

Timepoint

Screening, week 8

Method of measurement

Physician assessment and Endoscopy

Secondary outcomes**1****Description**

Percentage of patients achieving clinical remission based on MAYO score at weeks 8 and 30Clinical remission: MAYO score of 2 points or lower, with no individual subscore exceeding 1 point.

Timepoint

Screening, week 8, week 30

Method of measurement

Physician assessment and Endoscopy

2**Description**

Percentage of patients achieving clinical response based on MAYO Score at week 30

Timepoint

Screening, week 30

Method of measurement

Physician assessment and Endoscopy

3**Description**

Percentage of patients achieving mucosal healing at weeks 8 and 30Mucosal healing: Absolute subscore for Endoscopy of 0 or 1.

Timepoint

Screening, week 8, week 30

Method of measurement

Endoscopy

4**Description**

The changes of the IBDQ score at week 30 in comparison to week 0

Timepoint

Week 0, week 30

Method of measurement

IBDQ questionnaire

5**Description**

Changes of Fecal calprotectin at week 30 in comparison to the screening

Timepoint

Screening, week 30

Method of measurement

Stool biochemistry test

6**Description**

Percentage of patients with reduced dose of prednisolone at week 30 in comparison to screening

Timepoint

Screening, week 30

Method of measurement

Physician assessment

Intervention groups**1****Description**

Intervention group: Infliximab (AryoGen Pharmed co., Iran), 5 mg/kg, intravenous infusion, at day 0 and weeks 2, 6, 14, and 22

Category

Treatment - Drugs

2**Description**

Control group: Remicade® (Infliximab, Janssen Immunology co., Belgium) 5 mg/kg, intravenous infusion, at day 0 and weeks 2, 6, 14, and 22

Category

Treatment - Drugs

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Sponsors / Funding sources

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Sponsor

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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
AryoGen Pharmed Company
Proportion provided by this source

100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable