Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 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

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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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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