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

Registrant information

Name
Nassim Anjidani

Name of organization / entity
Orchid Pharmed

Country
Iran (Islamic Republic of)

Phone
+98 21 4347 3000

Email address
amini@orchidpharmed.com

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
Street address
Central Building of TUMS, Ghods Ave., Keshavarz Blvd., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417653761

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

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Nasser Ebrahimi Daryani
Street address
Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
nasere@yahoo.com

2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Foroogh Alborzi Avanaki
Street address
Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
alborzi.foroogh@gmail.com

3

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Mohammad Taher
Street address
Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
Tahermdir@gmail.com

4

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Homayoun Vahedi Tafreshi
Street address
Ale-Ahmad Junc, Karegar Ave,Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
dr_vahedi@yahoo.com

5

Recruitment center
Name of recruitment center
Masoud clinic
Full name of responsible person
Amir Anoushirvani
Street address
No. 144, 19th Alley, North Kargar Ave
City
Tehran
Province
Tehran
Postal code
1439963553
Phone
+98 917 316 0616
Email
amiranush@gmail.com

6

Recruitment center
Name of recruitment center
Masoud Clinic
Full name of responsible person
Marjan Mokhtare
Street address
No. 144, Alley 19., North Kargar Ave
City
Tehran
Province
Tehran
Postal code
1439963553
Phone
+98 911 156 8597
Email
marjanmokhtare@yahoo.com

7

Recruitment center
Name of recruitment center
Professor Shahram Aghah Gastroenterology, Hepatology, and Endoscopy Specialty Clinic
Full name of responsible person
Shahram Agah

Street address
Unit 24, No. 1, 9th Alley, North Side of Kaj Square (Shahid Tehrani Moghadam), Saadat Abad
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 912 327 8615
Email
shahramagah@gmail.com

8

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Shabnam Shahrokh
Street address
Araabi St., ؛Yaman Ave., Chamran High Way, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2293 7031
Email
shabnamshahrokh@gmail.com

9

Recruitment center
Name of recruitment center
Faghihi Hospital
Full name of responsible person
Kamran Bagheri Lankarani
Street address
Next to the Faculty of Medicine, Karim Khan Zand Blvd
City
Shiraz
Province
Fars
Postal code
۷۱۳۴۸۴۶۱۱۴
Phone
+98 917 118 4083
Email
kblankarani@gmail.com

10

Recruitment center
Name of recruitment center
Pazh Clinic
Full name of responsible person
Hasan Vosoughinia
Street address
First Floor., Atieh Medical Building., Before Tak Complex., Between Dastgheib 33 and 35., Khayyam Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
9185811111
Phone
+98 915 310 0263
Email
vosoghiniah@mums.ac.ir

11

Recruitment center
Name of recruitment center
Salamat clinic of Alzahra Hospital Hospital
Full name of responsible person
Babak Tamizifar
Street address
Soffeh Blvd, Shahid Keshvari High Way
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 913 325 7859
Email
babaktamizifar@gmail.com

12

Recruitment center
Name of recruitment center
Salamat Clinic of Alzahra Hospital
Full name of responsible person
Hadi Abdollahi
Street address
Soffeh Blvd, Shahid Keshvari High Way
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 913 117 2760
Email
Hadi.abdolahi@yahoo.com

13

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Iraj Maleki
Street address

Razi Ave, Valie-Asr Blvd,

City
Sari

Province
Mazandaran

Postal code
48166 33131

Phone
+98 11 3304 4000

Email
iradj2001@yahoo.com

14

Recruitment center

Name of recruitment center
Guilan Gastroenterology and Liver Specialist Clinic

Full name of responsible person
Fariborz Mansour Ghanaei

Street address
Arsen Building, Imam Khomeini Ave., Before Heshmat Square

City
Rasht

Province
Guilan

Postal code
4136944501

Phone
+98 911 131 3787

Email
ghanaie@yahoo.com

15

Recruitment center

Name of recruitment center
Dr. Seyedhamid Moosavy clinic

Full name of responsible person
Seyedhamid Moosavy

Street address
Units 207 & 208, 2nd Floor, Arjin Building, Beginning of Seyyed Jamal-eddin Asadabadi Blvd, After the Daraii Intersection

City
Bandarabbas

Province
Hormozgan

Postal code
7914690066

Phone
+98 917 763 5854

Email
seyedhamid_moosavy@yahoo.com

16

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital

Full name of responsible person
Javad Shokri

Street address
Sargord Ghasemi Ave

City
Babol

Province
Mazandaran

Postal code
4716681451

Phone
+98 912 195 2294

Email
javadshokry@gmail.com

17

Recruitment center

Name of recruitment center
Masoud clinic

Full name of responsible person
Alireza Sima

Street address
No. 144, 19th Alley, North Kargar Ave

City
Tehran

Province
Tehran

Postal code
1439963553

Phone
+98 915 513 7188

Email
simaalireza@gmail.com

18

Recruitment center

Name of recruitment center
Firoozgar General Hospital

Full name of responsible person
Amir Hosein Faraji

Street address
Firoozgar Hospital, Beh Afarin St., Valiasr Square, Tehran.

City
Tehran

Province
Tehran

Postal code
1593748711

Phone
+98 912 825 1794

Email
Amir.hfaraji6@gmail.com

19

Recruitment center

Name of recruitment center
Salamat Medical Complex

Full name of responsible person
Mohammad Hossein Somi

Street address
Salamat Medical Complex, Eighth Floor, Pishghadam Bridge, Middle Ringroad, Tabriz

City
Tabriz
Province
East Azarbaijan
Postal code
5165741651
Phone
+98 914 313 6460
Email
Mhosseinsina@yahoo.com

20

Recruitment center
Name of recruitment center
Mehregan Hospital
Full name of responsible person
Mohammad javad zahedi
Street address
Mehregan Hospital, Kamyab St, Kerman
City
Kerman
Province
Kerman
Postal code
7614613191
Phone
+98 913 140 1208
Email
Zahedi@kmu.ac.ir

21

Recruitment center
Name of recruitment center
Dr. Bashiri Gastroenterology Clinic
Full name of responsible person
Homayoon Bashiri
Street address
Dr. Bashiri Gastroenterology Clinic, Day Building, Haj Mohammad Taghi Esfahani Street, Municipality Parking Lot, Kermanshah
City
Kermanshah
Province
Kermanshah
Postal code
6714636554
Phone
+98 918 131 0389
Email
hbashirimd@gmail.com

22

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Arash Mir Oliyaee
Street address
Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
Arashmiroliaee53@gmail.com

23

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Reza Taslimi
Street address
Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
Taslimir@yahoo.com

24

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Behshad Pazooki
Street address
Imam Khomeini Hospital, Keshavarz Blvd., Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
Behshad.pazooki@yahoo.com

25

Recruitment center
Name of recruitment center
Kourosh Clinic
Full name of responsible person
Homeira Ommati
Street address
Korosh Clinic, First Floor, Benyamin Building, Corner of Parastar 7, Ahmadabad, Mashhad

City
Mashhad
Province
Razavi Khorasan
Postal code
9176694152
Phone
+98 915 318 6759
Email
dr.homeira.ommati@gmail.com

26

Recruitment center
Name of recruitment center
Kourosh Clinic
Full name of responsible person
Mohammad Reza Farzanehfar
Street address
Korosh Clinic, First Floor, Benyamin Building, Corner of Parastar 7, Ahmadabad, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9176694152
Phone
+98 915 508 3486
Email
farzanehfm84@gmail.com

27

Recruitment center
Name of recruitment center
Dr Faghihi Hospital
Full name of responsible person
Ali Shahsavari
Street address
Dr Faghihi Hospital, Next to the Faculty of Medicine, Karim Khan Zand Boulevard, Shiraz
City
Shiraz
Province
Fars
Postal code
۷۱۳۴۸۴۶۱۱۴
Phone
+98 917 913 5108
Email
alishahsavari076@gmail.com

28

Recruitment center
Name of recruitment center
Shariati Hospital of Isfahan
Full name of responsible person
Hamid Mohajer
Street address
Shariati Hospital of Isfahan, First Taj al-Din Alley, Taj al-Din Alley, Sichan, Chahar Bagh Bala, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8173745384
Phone
+98 913 327 7156
Email
hamidmohajermd@gmail.com

29

Recruitment center
Name of recruitment center
Imam Ali Hospital
Full name of responsible person
Reyhaneh Jafarshad
Street address
Imam Ali Hospital, Azimieh, Resalat Three-Way, Karaj, Alborz Province
City
Karaj
Province
Alborz
Postal code
3154686695
Phone
+98 911 136 4161
Email
shad.reyhan@gmail.com

30

Recruitment center
Name of recruitment center
Imam Ali Hospital
Full name of responsible person
Mohsen Rajabnia Chenari
Street address
Imam Ali Hospital, Azimieh, Resalat Three-Way, Karaj, Alborz Province
City
Karaj
Province
Alborz
Postal code
3154686695
Phone
+98 935 771 9022
Email
Drrajabnia@gmail.com

31

Recruitment center
Name of recruitment center
Imam Ali Hospital
Full name of responsible person
Roham Gholami
Street address
Imam Ali Hospital, Azimieh, Resalat Three-Way, Karaj, Alborz Province

City
Karaj
Province
Alborz
Postal code
3154686695
Phone
+98 912 298 9204
Email
dr_rgholami@yahoo.com

32

Recruitment center
Name of recruitment center
Imam Ali Hospital
Full name of responsible person
Amir Abbas Vaezi
Street address
Imam Ali Hospital, Azimieh, Resalat Three-Way, Karaj, Alborz Province
City
Karaj
Province
Alborz
Postal code
3154686695
Phone
+98 912 361 5071
Email
Avaezi60@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
AryoGen Pharmed Company
Full name of responsible person
Mohammad Saffarioun
Street address
No. 140, 24th Km Tehran-Karaj Makhsous road
City
Karaj
Province
Alborz
Postal code
3164819712
Phone
+98 26 3610 6480
Email
contact@aryogen.com
Web page address
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

Contact
Name of organization / entity
Orchid Pharmed Co.
Full name of responsible person
Hamidreza Kafi
Position
Medical Department Manager
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
No 42, Attar St., Vanak Sq, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1994766411
Phone
+98 21 4347 3000
Email
Kafi.H@orchidpharmed.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Nasser Ebrahimi Daryani
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gastroenterology and Hepatology
Street address
Keshavarz Bldv, Imam Khomeini Hospital, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 912 923 2594

Email
nasere@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Orchid Pharmed Co.
Full name of responsible person
Hamidreza Kafi
Position
Medical Department Manager
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
No 42, Attar St., Vanak Sq, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1994766411
Phone
+98 21 4347 3000
Email
Kafi.H@orchidpharmed.com

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