Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

A randomised, double-blind, single-dose, active-controlled, crossover study in healthy subjects to demonstrate pharmacokinetic equivalence of AltebrelTM (produced by AryoGen Pharmed) and Enbrel:registered:(produced by Amgen Company)

Protocol summary

Summary
This is a single-dose trial with one administration of each product (AltebrelTM and Enbrel®). Each subject will participate in two treatment periods, and will be randomised to receive AltebrelTM or Enbrel® in a crossover fashion. The subjects will be hospitalized in the trial site for 24 hours after dosing for serial pharmacokinetic sampling. The subjects will be requested to visit the trial site 36, 48, 60, 72, 96, 120, 144, 168, 216, 312 and 480 h after dose administration for blood sampling and evaluation of safety variable and tolerability.

General information

Acronym

IRCT registration information
IRCT registration number: **IRCT2016033021315N4**
Registration date: **2017-06-06, 1396/03/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date
2017-06-06, 1396/03/16

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
Recruitment complete

Funding source
AryoGen Pharmed company

Expected recruitment start date
2016-12-04, 1395/09/14
Expected recruitment end date
2017-03-15, 1395/12/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A randomised, double-blind, single-dose, active-controlled, crossover study in healthy subjects to demonstrate pharmacokinetic equivalence of AltebrelTM (produced by AryoGen Pharmed) and Enbrel:registered:(produced by Amgen Company)

Public title
Comparison between AltebrelTM and Enbrel®
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion: 1)Provide written IC to participate in the trial and to comply with the trial procedures. 2)Take written informed consent to participate in the trial and to abide by the trial restrictions. 3)Be healthy male between the ages of 18 and 55 years. Healthy is defined as no clinically relevant abnormalities identified by a detailed medical history, complete physical examination including blood pressure and heart rate measurement, 12 lead

ECG and clinical laboratory tests. 4)Have a body mass index between 20.0 and 30 kg/m², inclusive 5)Have Chest X-ray with no evidence of current, active TB or previous (inactive) TB, general infections, heart failure, malignancy, or other clinically significant abnormalities taken at Screening or within 24 weeks prior to Day 1 and read by a qualified radiologist. Exclusion: 1.Being doubtful about their availability to complete the trial. 2.history and/or current presence of clinical significant atopic allergy, hypersensitivity or allergic reactions, also including known or suspected clinically relevant drug hypersensitivity to any components of the test and reference IMP formulation or comparable drugs. 3.Active or latent Tuberculosis or who have a history of Tuberculosis. 4.history of invasive systemic fungal infections or other opportunistic infections 5.systemic or local infection, a known risk for developing sepsis and/or known active inflammatory process 6.serious infection associated with hospitalisation and/or which required intravenous antibiotics 7.history of and/or current cardiac disease 8.Have received live vaccine(s) within 30 days prior to Screening or who will require live vaccine(s) between Screening and the final study visit. 9.Intake medication with a half-life > 24 h within 1 month or 5 half-lives of the medication prior to the first administration of IMP. 10.Positive pre-study Hepatitis B surface antigen or positive Hepatitis C antibody. A positive test for HIV antibody. 11.History of CNS demyelinating disorders in family (MS) 12.Have a history of smoking >10 cigarettes per day

Age
From **18 years** old to **55 years** old

Gender
Male

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of medical science

Street address
District 6, Poursina St.

City
Tehran

Postal code

Approval date
2017-04-18, 1396/01/29

Ethics committee reference number
IR.TUMS.VCR.REC.1396.2089

Health conditions studied

1

Description of health condition studied
rheumatoid arhtritis

ICD-10 code
M05, M06.9

ICD-10 code description
Seropositive rheumatoid arthritis, Rheumatoid arthritis, unspecified

Primary outcomes

1

Description
Cmax of etanercept

Timepoint
0, 6, 12, 24, 36, 48, 60, 72, 96, 120, 144, 168, 216, 312 and 480 hours

Method of measurement
ELISA

2

Description
AUC infinite of etanercept

Timepoint
0, 6, 12, 24, 36, 48, 60, 72, 96, 120, 144, 168, 216, 312 and 480 hours

Method of measurement
Calculation

Secondary outcomes

1

Description
AUClast of etanercept

Timepoint
0, 6, 12, 24, 36, 48, 60, 72, 96, 120, 144, 168, 216, 312 and 480 hours

Method of measurement
calculation

2

Description
tmax of etanercept

Timepoint

0, 6, 12, 24, 36, 48, 60, 72, 96, 120, 144, 168, 216, 312 and 480 hours

Method of measurement

calculation

3

Description

t½ of etanercept

Timepoint

0, 6, 12, 24, 36, 48, 60, 72, 96, 120, 144, 168, 216, 312 and 480 hours

Method of measurement

calculation

4

Description

Volume of distribution (VD) of etanercept

Timepoint

0, 6, 12, 24, 36, 48, 60, 72, 96, 120, 144, 168, 216, 312 and 480 hours

Method of measurement

calculation

5

Description

Clearance (CL) of etanercept

Timepoint

0, 6, 12, 24, 36, 48, 60, 72, 96, 120, 144, 168, 216, 312 and 480 hours

Method of measurement

calculation

6

Description

Adverse events (AE)

Timepoint

0, 6, 12, 24, 36, 48, 60, 72, 96, 120, 144, 168, 216, 312 and 480 hours

Method of measurement

physical Examination

Intervention groups

1

Description

a prefilled syringe dose of AltebrelTM (25 mg/0.5mL) to be administered as a single subcutaneous injection

Category

Treatment - Drugs

2

Description

a prefilled syringe dose of Enbrel® (25 mg/0.51mL) to be administered as a single subcutaneous injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Orchid Pahrmed Company

Full name of responsible person

Somayeh Amini

Street address

4th floor, No. 74, Across Faculty of Food Technology Shahid Beheshti University, Shahid Hafezi Street, Farahzadi Blvd., Shahrake Gharb

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

AryoGen Pharmed Company

Full name of responsible person

Somayeh Amini

Street address

no 2, Emad Khorassani D.D, Derakhti St, Dadman Blvd, Shahrake Gharb

City

Tehran

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Orchid Pharmed Company

Full name of responsible person

Somayeh Amini

Position

MedicalDepartment Manager/Pharm.D

Other areas of specialty/work

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Person responsible for scientific inquiries

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Other areas of specialty/work
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Somayeh Amini
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty