Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

comparison of the effect of Adalimumab and Infleximab in patients with Ankylosing Spondilitis presenting to Alzahra hospital

Protocol summary

Study aim
Determination and comparison of the efficacy of Adalimumab and Infliximab in patients with ankylosing spondylitis

Design
parallel group semi-randomized double blinded phase 3 clinical trial on 80 patients

Settings and conduct
Ankylosing spondylitis patients refering to Alzahra Hospital Clinic in 1397-1398 will enter the study and will be divided into two groups A (recipient of Adalimumab) and B (recipient of Infliximab) based on odd or even appointment numbers. Each patient will be evaluated on 0 (basic visit), 1 (2 months after the start of treatment) and 2 (4 months after the start of treatment) by a rheumatologist other than the patient's physician who is not aware of the patient's medication. The designed questionnaire will be completed by the rheumatologist .

Participants/Inclusion and exclusion criteria
Patients with known AS (according to the American College of Rheumatology) who have not responded to other treatments (at least 3 months of treatment with 2 NSAIDs) and are candidates for biological drugs. People who have contraindications to receiving anti-TNF drugs include people who have an active infection or are at high risk for infection, people who have cancer, a history of systemic lupus erythematosus, multiple sclerosis, and an autoimmune disease.

Intervention groups
Patients with an odd appointment number will be in group A and be treated with adalimumab once every 2 weeks at a dose of 40 mg per kilogram, and patients with an even appointment number will be in group B and be treated with Infliximab at a loading dose of 5 mg per kilogram in week 0-2-6 and then every 6 weeks.

Main outcome variables
BASDAI score, CRP, ESR, enthesitis, joint arthritis, occipital to wall distance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200412047047N1**
Registration date: **2020-05-19, 1399/02/30**
Registration timing: **prospective**

Last update: **2020-05-19, 1399/02/30**
Update count: **0**

Registration date
2020-05-19, 1399/02/30

Registrant information

Name
Marjan Golshani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3261 8928

Email address
golshani@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-21, 1399/03/01

Expected recruitment end date
2020-07-20, 1399/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

comparison of the effect of Adalimumab and Infleximab in patients with Ankylosing Spondilitis presenting to Alzahra hospital

Public title
comparison of the effect of Adalimumab and Infleximab in patients with Ankylosing Spondilitis presenting to Alzahra hospital

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with known AS according to the American College of Rheumatology not responded to at least 3 months of treatment with 2 different NSAIDs candidates for initiating biological drugs.

Exclusion criteria:
having contraindications to receiving anti-TNF drugs including active infection or being at high risk for infection past medical history of cancer past medical history of systemic lupus erythmatosis, past medical history of multiple sclerosis past medical history of an autoimmune disease.

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients entered to the study; 2 months and 4 months after the basic visit and starting treatment with one of the two drugs used in the study will go to the clinic and will be evaluated by a rheumatologist other than the patient's physician who is not aware of the patient's medication. The designed questionnaire will be completed and then the questionnaires will be analyzed by an analyst who is unaware of the type of medication received by the patients and the results will be compared.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committe of esfahan university of medical sciences

Street address
Isfahan university of medical sciences, Hezarjarib street, esfahan

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Approval date
2020-03-18, 1398/12/28

Ethics committee reference number
IR.MUI.MED.REC.1398.736

Health conditions studied

1

Description of health condition studied
Ankylosing Spondylitis

ICD-10 code
M45

ICD-10 code description
Ankylosing spondylitis

Primary outcomes

1

Description
BASDAI score

Timepoint
Basic visit, 2 months and 4 months after starting biological drug

Method of measurement
Questionnaire filled by a rheumatologist

Secondary outcomes

1

Description
Schober test

Timepoint
Basic visit, 2 months and 4 months after starting biologic drug

Method of measurement
measured by a rheumatologist by a meter

2

Description
CRP level

Timepoint
Basic visit, 2 months and 4 months after starting biologic drug
Method of measurement
laboratory

3

Description
ESR
Timepoint
Basic visit, 2 months and 4 months after starting biologic drug
Method of measurement
laboratory

4

Description
enthesitis
Timepoint
Basic visit, 2 months and 4 months after starting biologic drug
Method of measurement
examination by a rheumatologist

5

Description
occiput-wall distance
Timepoint
Basic visit, 2 months and 4 months after starting biologic drug
Method of measurement
examination by a rheumatologist using a meter

Intervention groups

1

Description
Intervention group: Patients in group A will be treated with adalimumab once every 2 weeks after first visit at a dose of 40 mg per kilogram.Adalimumab under the brand name Cinnora, owned by the pharmaceutical company Orchid pharmed, will be used subcutaneously after the initial training; by the patients themselves.
Category
Treatment - Drugs

2

Description
Intervention group: Patients in group B will be treated with infliximab at a loading dose of 5 mg per kilogram in week 0-2-6 after first visit and then every 6 weeks. Infliximab, under the brand name Remicade, owned by the pharmaceutical compamy JANSSEN (the importer company is Behestan Daru) requires temporary hospitalization for use. After premedication with hydrocortisone and chlorpheniramine, every 100 mg of infliximab is diluted with 250 cc of normal saline solution and infused over 2 to 3 hours. After receiving the drug, the patient will be discharged if he is in good general condition and has stable vital signs.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Marjan Golshani
Street address
Alzahra Hospital, Soffe Ave, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 1668 5555
Email
golshani@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo javanmard
Street address
Internal Medicine Department, Isfahan University of medical Sciences< Hezarjerib Ave
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
golshani@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Marjan Golshani
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Isfahan university of medical sciences, Hezarjarib street, Isfahan
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3261 8928
Email
golshani@med.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Marjan Golshani
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Isfahan university of medical sciences, Hezarjarib street, Isfahan
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3261 8928
Email
golshani@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Marjan Golshani
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Isfahan University of Medical Sciences, Hezarjarib Street, Isfahan
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3261 8928
Email
golshani@med.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Analyzed data will be available
When the data will become available and for how long
it will be available 6 months after publication
To whom data/document is available
this will be available only for those who work in academic institutions
Under which criteria data/document could be used
in response to email requests, the analysis of data will be sent. using the analysis without indicating the reference is forbidden.
From where data/document is obtainable
requests via email to the golshani@med.mui.ac.ir (responsible for scientific inquiries)
What processes are involved for a request to access data/document
after recieving email, it will be replied in one month.
Comments