

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

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

#### Protocol summary

##### Study aim

Determination and comparison of the efficacy of Adalimumab and Infleximab 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 referring 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 Infleximab) 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 Infleximab 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 Spondylitis presenting to Alzahra hospital

**Public title**

comparison of the effect of Adalimumab and Infleximab in patients with Ankylosing Spondylitis 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**

Isfahan

**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 company 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

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Isfahan

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**Postal code**

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+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

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8174673461

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+98 31 3668 0048

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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

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**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**

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**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

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**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 receiving email, it will be replied in one month.

**Comments**

