

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Effect of amidronate and immunosuppressive medications in treatment of patients with ankylosing spondylitis

Protocol summary

Summary

Objectives: The beneficial effects of both drugs, immunosuppressive drugs are pamidronate and improve clinical protests in patients with Ankylosing Spondylitis has been shown in many studies, but whether Pamydronate with fewer side effects can be a good alternative for immunosuppressive drugs safety, is questionable. This study aimed to investigate the effect of a drug class will be conducted. Design: This study is a randomized controlled trial. Setting and conduct: The samples included patients with a final diagnosis of ankylosing spondylitis (with the classification criteria New York) to receive care and treatment in the clinic of Rasoule Akram hospital During the year 1395 in Tehran were randomly divided into two groups (the intervention and control group). Inclusion criteria: None of the patients had not received until study drug, and PPD test and Viral markers were negative in them. Exclusion criteria: the occurrence of side-effects and the unwillingness of the patient to continue treatment Intervention : Study participants were randomly assigned to two groups received therapy with Pamidronate 90 mg IV for 6 months (n = 25) or medications that suppress the immune system based on standard protocols (n=16). Main outcome measures: To determine the effects of the questionnaire (BASDAI), and (BASFI), and evaluation of Health Questionnaire (HAQ) at two time points at baseline and after six months and laboratory tests such as the Erythrocyte sedimentation rate (ESR) and C Protein reactive (CRP) will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030813565N3**

Registration date: **2017-05-06, 1396/02/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-06, 1396/02/16

Registrant information

Name

Parastoo Amiri

Name of organization / entity

Shaheed Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 2220 2563

Email address

amiri.parasto@gmail.com

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-10-12, 1395/07/21

Expected recruitment end date

2016-12-05, 1395/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of amidronate and immunosuppressive medications in treatment of patients with ankylosing spondylitis

Public title

Comparing amidronate and immunosuppressive medications in treatment of patients with ankylosing spondylitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: None of the patients were not received until study drug, PPD test and Viral markers were negative
Exclusion criteria: the occurrence of side-effects; Patient unwillingness to continue the study

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 41

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Besides Milad Tower, Shahid Hemmat Highway,

City

Tehran

Postal code**Approval date**

2017-01-11, 1395/10/22

Ethics committee reference number

IR.IUMS.REC.1395.9221160001

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**

CRP

Timepoint

0,6m

Method of measurement

labratory

2**Description**

BASDAI questionnaire

Timepoint

0,6m

Method of measurement

BASDAI questionnaire

3**Description**

BASFA questionnaire

Timepoint

0,6m

Method of measurement

BASFA questionnaire

4**Description**

ESR

Timepoint

0,6m

Method of measurement

labratory

Secondary outcomes**1****Description**

HAQ questionnaire

Timepoint

0,6

Method of measurement

questionnaire

Intervention groups**1****Description**

Pamidronate 90 mg IV Intervention group

Category

Treatment - Drugs

2

Description

Retuximab 1000mg q14days two days control group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology Clinic of Hazrate Rasool Hospital

Full name of responsible person

Dr Seyyed Mohammadreza Vaziri

Street address

Hazrate Rasool Hospital, Sattar Khan St, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr seyed Ali Javad Mousavi

Street address

Besides Milad Tower, Shahid Hemmat Highway, Tehran

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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

Vice chancellor for research, Iran University of Medical Sciences

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

Iran University of Medical Sciences

Full name of responsible person

Seyyed Mohammad Reza Vaziri

Position

Internal Medicine Resident

Other areas of specialty/work

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>