

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Evaluatoin of intravenous pamidronate effect on disease activity in patients with rheumatoid arthritis

Protocol summary

Summary

The goal of this study is evaluation of the effect of intravenous Pamidronate on rheumatoid arthritis disease activity (DAS28 score). The study population includes patients referred to the Rheumatology Clinic of Alzahra Hospital. Sample size in this study is 37 people. The intervention under study is infusion of 60 mg Pamidronate intravenously each month for three months. Study starts at the fall 2009 and continues until winter 2011. The primary endpoint is improvement of clinical symptoms and laboratory parameters of patients who have injected Pamidronate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138801051778N1**
Registration date: **2010-04-06, 1389/01/17**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-04-06, 1389/01/17

Registrant information

Name

Mansour Salesi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1265 1983

Email address

salesi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellery of research, Isfahan University of Medical Sciences

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluatoin of intravenous pamidronate effect on disease activity in patients with rheumatoid arthritis

Public title

Pamidronate and disease activity in rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Rheumatoid arthritis patients who don't have enough clinical and laboratory response to conventional disease modifying anti rheumatic drugs (DMARDs). Exclusion criteria: patients who don't want to have injection or had drug allergy or hypersensitivity, Drug reaction in the course of injection or after that, Lapse from study, Immigration or death.

Age

From **16 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 37
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan University of Medical Sciences
Street address
Hezar Jarib Boulevard
City
Isfahan
Postal code
8158697851
Approval date
2009-03-18, 1387/12/28
Ethics committee reference number
187074

Health conditions studied

1

Description of health condition studied

Rheumatoid arthritis
ICD-10 code
M05
ICD-10 code description
Seropositive rheumatoid arthritis

Primary outcomes

1

Description

Disease activity
Timepoint
Before of injection, every month until 3 months, then 6 months after first injection
Method of measurement
DAS28

Secondary outcomes

1

Description

Anti inflammatory effect of pamidronate
Timepoint
Before of injection, every month until 3 months, then 6 months after first injection.
Method of measurement
DAS28, ESR, VAS

Intervention groups

1

Description

Infusion of 60 mg Pamidronate intravenously each month for three months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital
Full name of responsible person
Mansour Salesi
Street address
Sofe Avenue
City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellorry of research
Full name of responsible person
Dr Fallah
Street address
No#4 building, vice chancellorry of research, Isfahan
University of Medical Sciences
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellorry of research
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

Isfahan University of Medical Sciences

Full name of responsible person

Mansour Salesi

Position

Rheumatologist/Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Person responsible for scientific inquiries

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Position

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Other areas of specialty/work

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City

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8158697851

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