

# 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**

**Street address**

Alzahra Hospital

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## Person responsible for updating data

### 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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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Mansour Salesi

**Position**

Rheumatologist/Assistant Professor

**Other areas of specialty/work**

**Street address**

Alzahra Hospital

**City**

Isfahan

**Postal code**

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*