

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### A randomized clinical trial comparing the effect of methylprednisolone and dexamethasone pulse in the control of rheumatoid arthritis flare up

#### Protocol summary

##### Summary

**Objectives:** The aim of this study is the comparison of the efficacy and safety of dexamethasone and methylprednisolone pulse in the management of rheumatoid arthritis flare up. **Design, setting and conduct:** In a randomized double blind study in Emam Reza hospital of Tabriz University of Medical Sciences, rheumatoid arthritis patients after explaining the study aims and obtaining written informed consent will recruit to the study. They will divide accidentally according to the two last number of their document to the two groups. Disease activity of all patients will be measured by the disease activity score 28 (DAS28). **Participants:** Rheumatoid arthritis patients which their disease diagnosed according the American college of rheumatology 2011 criteria and have severely active disease (DAS28>5.2). **Exclusion criteria:** Congestive heart failure; active infection; hypokalemia ( $K^+ < 3.5$ ); systolic BP>180 or diastolic BP>100; diabetes; pregnancy **Intervention:** A group of patients will receive methylprednisolone 1gr/d IV for 3 days and another group dexamethasone 120mg/d IV for 3 days. In both groups after pulse therapy prednisolone 15mg/d in divided doses will be started. All patients will be visited before intervention, at Fourth day (one day after intervention) and one month later. DAS 28 will be measured by a rheumatologist who doesn't know the patients received methylprednisolone or dexamethasone. **Main outcome measures:** Disease activity will be measured by the DAS28. The clinical examination will be performed by a rheumatologist and DAS28 will be calculated using the numbers of swollen and tender joints, C-reactive protein (CRP) and patient general health by the patient using visual analog scale (VAS) .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112066975N2**

Registration date: **2011-12-27, 1390/10/06**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2011-12-27, 1390/10/06

##### Registrant information

###### Name

Alireza Khabbazi

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1337 3966

###### Email address

khabbazia@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2012-02-01, 1390/11/12

##### Expected recruitment end date

2012-07-01, 1391/04/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A randomized clinical trial comparing the effect of

methylprednisolone and dexamethasone pulse in the control of rheumatoid arthritis flare up

### Public title

A randomized clinical trial comparing the effect of methylprednisolone and dexamethasone pulse in the control of rheumatoid arthritis flare up

### Purpose

Treatment

### Inclusion/Exclusion criteria

Inclusion criteria: DAS28>5.2 Exclusion criteria: Congestive heart failure; active infection; hypokalemia (K+<3.5); systolic BP>180 or diastolic BP>100; diabetes; pregnancy

### Age

From **16 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **50**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic committee of Tabriz University of Medical Sciences

##### Street address

Four floor, Ethic committee, Vice chancellor for research, Faculty of medicine, Tabriz University of Medical Sciences

##### City

Tabriz

##### Postal code

5166614766

##### Approval date

2011-08-07, 1390/05/16

##### Ethics committee reference number

5.4.3861

## Health conditions studied

### 1

#### Description of health condition studied

Rheumatoid arthritis

#### ICD-10 code

M06.9

#### ICD-10 code description

Rheumatoid arthritis, unspecified

## Primary outcomes

### 1

#### Description

Disease activity

#### Timepoint

1 month

#### Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Complications of treatment

#### Timepoint

daily for 3 days

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

methylprednisolone 1gr/d IV for 3 days

#### Category

Treatment - Drugs

### 2

#### Description

dexamethasone 120mg/d IV for 3 days

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rheumatology Research Team, Tabriz University of Medical Sciences

##### Full name of responsible person

Alireza khabbazi

##### Street address

Four floor, Rheumatology Research Team, Emam

Reza hospital, University street

**City**  
Tabriz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tabriz University of Medical Sciences

**Full name of responsible person**

Ali Meshkini

**Street address**

Four floor, Vice chancellor for research, Faculty of Medicine, Tabriz University of Medical Sciences

**City**

Tabriz

**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, Tabriz 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

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Rheumatology Research Team, Tabriz University of Medical Sciences

**Full name of responsible person**

Alireza Khabbazi

**Position**

Assistant professor of medicine/Rheumatologist

**Other areas of specialty/work**

**Street address**

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**Postal code**

5167747899

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khabbazia@tbzmed.ac.ir; dr\_khabbazi@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Rheumatology Research Team, Tabriz University of Medical Sciences

**Full name of responsible person**

Alireza Khabbazi

**Position**

Assistant professor of medicine/Rheumatologist

**Other areas of specialty/work**

**Street address**

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**City**

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## 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*