

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

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Position

Assistant professor of medicine/Rheumatologist

Other areas of specialty/work

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Web page address

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