

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

A randomized clinical trial considering the effect of vitamin D supplementation on control of disease activity in rheumatoid arthritis patients patients

Protocol summary

Summary

Objectives: The aim of this study is evaluation of the safety and efficacy of vitamin D in the management of rheumatoid arthritis patients. **Design, setting and conduct:** In a randomized single blind study in specialty clinics' of Tabriz University of Medical Sciences, rheumatoid arthritis patients after explaining the study aim and obtaining written informed consent will recruit to the study. They will divide accidentally according to the two last number two groups. Disease activity of all patients will be measured by Disease activity score 28 (DAS28). **Participants:** Rheumatoid arthritis patients which their disease diagnosed according the American college of rheumatology 1987 criteria and have active disease (DAS28>2.6). **Exclusion criteria:** Use of vitamin D supplements in the past 6 months; pregnancy; liver and kidney disease; treatment with anticonvulsion drugs **Intervention:** A group of patients will receive 50,000 IU of vitamin D monthly for 6 months and control group nothing. All patients will be visited every 2 months and DAS 28 will be measured by a rheumatologist who doesn't know the patients received vitamin D or no. Two groups will treat with a standard protocol with prednisolone 5-15 mg/d, escalating dose of methotrexate 7.5-25 mg/week and hydroxychloroquine 400 mg/d. In the treatment resistant patients we will add sulfasalazin 1500-2000 mg/d and then cyclosporine 3 mg/kg/d. **Main outcome measures:** Disease activity measured by DAS28. The clinical examination was done by a rheumatologist and DAS28 was 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) [online at www.das-score.nl]. Paired t test will be use for considering DAS28 in treatment and control group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110016975N1**

Registration date: **2011-10-18, 1390/07/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-10-18, 1390/07/26

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

2011-11-11, 1390/08/20

Expected recruitment end date

2012-02-09, 1390/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized clinical trial considering the effect of vitamin D supplementation on control of disease activity in rheumatoid arthritis patients patients

Public title

A randomized clinical trial considering the effect of vitamin D supplementation on control of disease activity in rheumatoid arthritis patients patients

Purpose

Treatment

Inclusion/Exclusion criteria

Exclusion criteria: Use of vitamin D supplements in the past 6 months; pregnancy; liver and kidney disease; treatment with anticonvulsion drugs drugs

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

-

Secondary trial Id

-

Registration date

empty

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

Ethic committee of Tabriz university of medical sciences

Street address

Ethic committee, Vice chancellor for research, Faculty of medicine, Tabriz university of medical sciences,

Faculty of medicine,

City

Tabriz

Postal code**Approval date**

2011-01-17, 1389/10/27

Ethics committee reference number

8958

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

6 months

Method of measurement

Questionnaire

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

Complications of treatment

Timepoint

Before intervention and every two months.

Method of measurement

Questionnaire

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

No intervention will perform in control group.

Category

N/A

2**Description**

Twenty five hydroxy Vitamin D tablet 50000 unit each month orally will given for 6 months to intervention group.

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

Rheumatology Research Team, Emamreza hospital, University street, Tabriz

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

Other areas of specialty/work**Street address**

Rheumatology Research Team, Internal Medicine Department, Emam reza hospital

City

Tabriz

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+98 41 1337 3966

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khabbazia@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

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