Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 41 1337 3966

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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 commitee of Tabriz university of medical sciences

Street address
Ethic commitee, 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, Facylty 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

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Rheumatology Research Team, Internal Medicine Department, Emam reza hospital

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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