

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the same dose of oral and parenteral vitamin D in treatment of vitamin D insufficiency

Protocol summary

Summary

The aim of this study is to compare the effectiveness of different methods of vitamin D administration in patients who are suffering from vitamin D deficiency or inadequacy. Serum 25 (OH) D3 will be measure 3 months and 6 months after the administration of vitamin D. This is an open label randomized clinical trial or interventional study. The study population: All patients in whom level of 25 (OH) D3 is in the range of deficient or inadequate and are eligible to enter. Exclusion criteria: People who are exposed to out of the ordinary types of light; are pregnant; have malabsorption diseases (based on clinical practice.) Inclusion criteria: Age between 18 to 60 years, no evidence of liver or kidney disease. 92 subjects were randomly divided into two groups with block randomization method. Oral vitamin D group: 46 patients received six pearls of 50.000 units oral vitamin D. Parenteral vitamin D group: 46 patients received one IM injection of 300.000 unit bolus vitamin D. After three and six months the effects of these methods will be assessed by measuring blood levels of 25 OH D3.

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

m.zabihyeganeh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

goverment

Expected recruitment start date

2010-10-15, 1389/07/23

Expected recruitment end date

2011-03-18, 1389/12/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010174950N1**

Registration date: **2010-11-22, 1389/09/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-11-22, 1389/09/01

Registrant information

Name

Mozhdeh Zabihyeganeh

Scientific title

Comparison of the same dose of oral and parenteral vitamin D in treatment of vitamin D insufficiency

Public title

What is the best way for treatment of vitamin D deficiency and insufficiency?

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients referred to the Rheumatology clinic of Firouzgar Hospital for whom the level of 25(OH) D3 is in the range of inadequate or insufficient. Exclusion criteria: 1 - People who consume vitamin D during the study orally or have plans to inject outside the study program 2 - People who are exposed to out of the ordinary types of light 3 - Pregnant 4 -

malabsorption diseases (based on clinical practice.) 5 - age less than 18 years of age. 6 -age more than 60 years of age. 7 - Liver or kidney diseases

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran university of medical sciences

Street address

Shahid Hemat high way

City

Tehran

Postal code

Approval date

empty

Ethics committee reference number

1.849

Health conditions studied

1

Description of health condition studied

vitamine D defiecy

ICD-10 code

E 55

ICD-10 code description

Vitamin D deficiency

Primary outcomes

1

Description

serum vitamin D level

Timepoint

Before intervention, 3 month after treatment, 6 month after treatment.

Method of measurement

RIA laboratory test by using Biosource Europe's kit

Secondary outcomes

empty

Intervention groups

1

Description

Oral vitamin D group: 46 patients received six pearls of 50.000 units oral vitamin D

Category

Treatment - Drugs

2

Description

Parenteral vitamin D group: 46 patients received one IM injection of 300.000 unit bolus vitamin D

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar Hospital

Full name of responsible person

Mozhdeh Zabihiyeganeh, Assistant professor of rheumatology

Street address

Unit 10, No.133, Mehr building, 9th Golestan, Pasdaran street.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran university of medical sciences

Full name of responsible person

Maziar Moradilale

Street address

Vice chancenllor for research, Tehran university of medical sciences,Hemat high way,

City

Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

Name of organization / entity
Tehran university of medical sciences
Full name of responsible person
mozhddeh zabihyeganeh
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Person responsible for updating data

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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