

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of Oral & Intramuscular injection form of Vitamin D prescription on the Serum 25-Hydroxy-vitamin D level in patients with vitamin D deficiency

Protocol summary

Study aim

Comparison of Oral & Intramuscular injection form of Vitamin D prescription on the Serum 25-Hydroxy-vitamin D level in patients with vitamin D deficiency

Design

Two arm parallel group clinical trial, double blinded, non-randomized, phase 3 on 150 patients in each group

Settings and conduct

This study is done on patients referred to endocrinology & rheumatology clinics of Ayatollah Rouhani`s hospital. Only the clinician knows the drug prescribed in every group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Everybody older than 18 years referred to endocrinology & rheumatology clinic that have serum 25(OH)D3 level lower than 20 ng/mL Exclusion criteria: 1- patient dissatisfaction 2- Known gastrointestinal disease effective on vitamin D absorption 3- Low serum albumin level 4- Chronic Renal Failure 5- Hepatic failure 6- Taking medication effective on vitamin D & calcium metabolism 7- Pregnancy 8- Malignancy 9- Untreated thyroid disorder 10- Primary hyperparathyroidism

Intervention groups

In one group, vitamin D in the form of 50000 U orally pearl is prescribed weekly, up to 8 weeks, and in another group an single dose of intramuscular injection of 300000 U ampule is prescribed.

Main outcome variables

Determining of the most appropriate & the most reliable method of replacement of vitamin D deficiency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191030045277N1**

Registration date: **2020-06-23, 1399/04/03**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-23, 1399/04/03**

Update count: **0**

Registration date

2020-06-23, 1399/04/03

Registrant information

Name

mohammadali bayani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3223 8284

Email address

bayanima49@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-29, 1398/10/08

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Oral & Intramuscular injection form of Vitamin D prescription on the Serum 25-Hydroxy-vitamin D level in patients with vitamin D deficiency

Public title

Comparison of Oral & Intramuscular injection form of Vitamin D in patients with vitamin D deficiency

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Every body older than 18 years Serum 25(OH)D3 level lower than 20 ng/mL

Exclusion criteria:

Patient dissatisfaction Known gastrointestinal disease effective on vitamin D absorption Low serum albumin level Chronic Renal Failure Hepatic failure Taking medication effective on vitamin D & calcium metabolism Pregnancy Malignancy Untreated thyroid disorder Primary hyperparathyroidism

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Based on the ticket number being even or odd, the patient will placed on group A or B, and one of the oral or injection form of vitamin D will prescribed by clinician. The patient doesn't know the way of treatment of others. The researcher, the outcome evaluator, and data analyzer know the group A & B results only, not the form of drug that was prescribed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Ganj afruz

City

Babol

Province

Mazandaran

Postal code

۴۷۱۷۶۴۷۷۴۵

Approval date

2019-12-29, 1398/10/08

Ethics committee reference number

IR.MUBABOL.HRI.REC.1398.267

Health conditions studied

1

Description of health condition studied

Vitamin D deficiency

ICD-10 code

E55

ICD-10 code description

Vitamin D deficiency

Primary outcomes

1

Description

Serum level of vitamin D

Timepoint

Measurement of serum level of vitamin D at the beginning of study & the end of eighth week

Method of measurement

Based on measurement of serum level of vitamin D in laboratory

Secondary outcomes

1

Description

Serum level of vitamin D

Timepoint

Measurement of serum level of vitamin D at the beginning of study & the end of eighth week

Method of measurement

Based on measurement of serum level of vitamin D in laboratory

Intervention groups

1

Description

Intervention group 1: For patients in this group, the pearl of vitamin D (D-vitin, the product of Zahravi's company) 50000 U weekly until eight weeks is prescribed, and serum level of vitamin D is measured at the end of eighth week again.

Category

Treatment - Drugs

2

Description

Intervention group 2: For patients in this group, injection form of vitamin D (the product of Osvah`s company) 300000 U single dose is prescribed, and serum level of vitamin D is measured at the end of eighth week after treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rohani Hospital

Full name of responsible person

Mohammadali Bayani

Street address

Ganj Afrooz Road, Babol Rohani Hospital

City

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47176-47745

Phone

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Email

info@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mohammadali Bayani

Street address

Ganj Afrooz Road, Babol Rohani Hospital

City

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Postal code

47176-47745

Phone

+98 11 3223 8309

Email

Info@mubabol.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mohammadali Bayani

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinologist and Metabolism Specialist

Street address

Ganj Afrooz Road, Babol Rohani Hospital

City

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Mohammadali Bayani

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinologist and Metabolism Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

A portion of the data related to the main topic is displayed.

When the data will become available and for how long

Start of access period 6 months after printing result.

To whom data/document is available

It will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

No special conditions

From where data/document is obtainable

Babol University of Medical Sciences, Ruhani`s hospital, Dr. Mohammad Ali Bayani

What processes are involved for a request to access data/document

Refer to Ruhani`s hospital and talk to Dr. Mohammad Ali Bayani and access to information

Comments