

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

comparing the effect of oral stripe and vitamin D3 pearl, in patients with vitamin D deficiency in single blind clinical trial

Protocol summary

Study aim

Comparing the effect of oral stripe and perl vitamin D in patients with vitamin D deficiency

Design

A clinical trial with a control group, with parallel groups, single blind, randomized

Settings and conduct

This study is a randomized, single blinded clinical trial (only analyst will not be aware of patients' grouping) on patients suffering from deficiency and inadequate vitamin D in a Golestan Hospital in 2012 for 2 months. Blindness in This study will be conducted as a single blind so that the statistical analyzer does not know which patients are present in the group.

Participants/Inclusion and exclusion criteria

The criteria for entering the patients are: 1. Reduce the level of vitamin D3 (25OH Vitamin D) from normal range ($<32\text{ ng / ml}$). 2. Age of patients older than 7 years; Exit criteria for the study include: 1. Drinking alcohol or drugs. 2. The patient will not be able to use Perl vitamin D3 or oral stripe. 3. Patients with hypercalciuria, hyperparathyroidism, hypothyroidism, patients taking anti-seizure drugs, anti-tuberculosis, typhylline and vitamin D supplements, and those with malabsorption syndrome, celiac disease, and liver and kidney failure. They will be out.

Intervention groups

In this study, 50 patients with reduced vitamin D3 will be selected from normal range ($32 > \text{ ng / ml}$). For all patients, serum vitamin D3 levels will be measured at the beginning of the study and at the end of the study (after 8 weeks). In this study, patients will be randomized into two groups. Which will be given to a perl group of vitamins D3 of 50,000 units once a week for 8 weeks (control group) and to another group of oral stretch form 2000 units per day.

Main outcome variables

vitamin D3 serum level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180408039235N1**

Registration date: **2018-07-11, 1397/04/20**

Registration timing: **retrospective**

Last update: **2018-07-11, 1397/04/20**

Update count: **0**

Registration date

2018-07-11, 1397/04/20

Registrant information

Name

Aryan Yousefi Fard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3443 9992

Email address

youseffard.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-05-31, 1397/03/10

Actual recruitment start date

2018-01-10, 1396/10/20

Actual recruitment end date

2018-02-14, 1396/11/25

Trial completion date

empty

Scientific title

comparing the effect of oral stripe and vitamin D3 pearl, in patients with vitamin D deficiency in single blind clinical trial

Public title
Evaluating the effectiveness of oral stripe and perl vitamin D in vitamin D deficiency

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Decreased vitamin D levels from normal range (32 ng / ml) Age of patients older than 7 years
Exclusion criteria:
Company dissatisfaction with the study Drinking alcohol or drugs The patient will not be able to use Perl vitamin D3 or oral strip Patients with hypercalciuria, hyperparathyroidism, hypothyroidism, patients taking anti-seizure drugs, anti-tuberculosis, typhylle and vitamin D supplements, and those with malabsorption syndrome, celiac disease, and liver and kidney failure

Age
From **7 years** old

Gender
Both

Phase
2

Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Replacement randomization method is used for randomization so that completely randomized individuals are divided into two groups. Curing: This study will be conducted as a single blind so that the statistical analyzer is from which group of patients were present.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study will be done side by side so that the statistical analyzer does not know which patients are present in the group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of Ahvaz Johndishapur University of Medical Sciences

Street address
Medical Sciences Blvd. Jundishapur University of Medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
15794-61357

Approval date
2018-05-12, 1397/02/22

Ethics committee reference number
IR.AJUMS.REC.1397.112

Health conditions studied

1

Description of health condition studied
Vitamin D deficiency

ICD-10 code
E55.9

ICD-10 code description
Vitamin D deficiency, unspecified

Primary outcomes

1

Description
Measuring serum vitamin D levels

Timepoint
8 Week

Method of measurement
Serum test

Secondary outcomes
empty

Intervention groups

1

Description
Control group: Pearl recipients of vitamin D, For 30 patients, 50,000 units of vitamin D (zhravi company) once a week were administered orally for 8 weeks (control group) .

Category
Treatment - Drugs

2

Description
Intervention group: Strip recipients of vitamin D, and for 30 others oral strip 2000 units of vitamin D (ramopharmin company) administered daily for 8 weeks.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Golestan Hospital

Full name of responsible person

Aryan Yousefi Fard

Street address

Johndishapour University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Reza Ganji

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Daneshjou Blvd, Johndishapur University of Medical
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Rg.pharm777@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Aryan Yousefi Fard

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available