Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

comparing the effect of oral stripe and vitamin D3 pearl, in patiens 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 inThis 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 (<32ng / 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> 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
yousefifard.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 patiens 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, typhylline 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

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ahvaz Golestan Hospital
Full name of responsible person
Aryan Yousefi Fard
Street address
Johondishapour University of Medical Sciences ,Medical Sciences Blvdahvaz, khozestan provice
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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 Sciences,
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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
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Medical Pharmacy
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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