Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing theVitamin-D level treatment with 50000IU weekly Vitamin D and 4000IU daily Vitamin-D in Chronic lymphocytic leukemia patients

Protocol summary

Study aim
Comparison between the efficacy of administering a dose of 50,000 weekly vitamin D supplements and 4,000 units of daily vitamin D supplementation in patients with chronic lymphocytic leukemia

Design
Clinical trials without control group, parallel group, double-blind, randomized trials

Settings and conduct
Double-blind study is done on patients referred to the Velayat hospital of Qazvin. Patients with chronic lymphocyte leukemia with vitamin D level less than 30 entering to the study after obtaining informed consent; and then are assigned to two groups by sealed envelope method. The first group receives daily 4000 units and the second group receives weekly 50000 units vitamin D for 3 months; and after 6 months the serum vitamin D level of the patients is measured.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with chronic lymphocyte leukemia that serum levels of vitamin D are less than 30 Exclusion criteria: hepatic failure, renal failure, vitamin D supplements during the last three months

Intervention groups
First group: Receive daily 4000 units vitamin D for 3 months Second group: Receive weekly 50000 units vitamin D for 3 months

Main outcome variables
Patient' tolerance to the dose

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180912041010N1**
Registration date: **2018-09-16, 1397/06/25**
Registration timing: **prospective**
Last update: **2018-09-16, 1397/06/25**
Update count: **0**

Registration date
2018-09-16, 1397/06/25

Registrant information

Name
Yazdan Zafari

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-31, 1397/08/09

Expected recruitment end date
2019-07-21, 1398/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing theVitamin-D level treatment with 50000IU weekly Vitamin D and 4000IU daily Vitamin-D in Chronic lymphocytic leukemia patients

Public title
A weekly dose comparison of 5000 units of vitamin D supplementation with a daily dose of 4,000 units in patients with chronic leukemia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic lymphocyte leukemia with a serum level of vitamin D of less than 30

Exclusion criteria:

Hepatic failure Renal failure Get Vitamin D supplementation in the last three months

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Sealed envelope

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher and patient are kept blind to the treatment assignment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical Sciences

Street address

Qazvin, Minoodar area, 22 Bahman BLVD.

City

Qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2018-04-17, 1397/01/28

Ethics committee reference number

IR.QUMS.REC.1397.055

Health conditions studied

1

Description of health condition studied

Chronic lymphocytic leukemia

ICD-10 code

C91.7

ICD-10 code description

Other lymphoid leukaemia

Primary outcomes

1

Description

Patient tolerance to the dose

Timepoint

6 months after intervention

Method of measurement

Vitamin D Serum level in the blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receive daily 4000 units vitamin D for 3 months

Category

Treatment - Drugs

2

Description

Intervention group: Receive weeky 5000 vitamin D units for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Educational and Treatment Center

Full name of responsible person

Dr. Mahnaz Abbasi

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Sponsors / Funding sources

1

Sponsor
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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
Qazvin University of Medical Sciences
Proportion provided by this source
50
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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Not applicable
Title and more details about the data/document
-
When the data will become available and for how long
-
To whom data/document is available
-
Under which criteria data/document could be used
-
From where data/document is obtainable
-
What processes are involved for a request to access data/document
-
Comments