Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Supplementation with vitamin D on anti aging protein klotho in old people

Protocol summary

Summary

This is a prospective, double-blinded, randomized study to evaluate the effects of vitamin D supplementation on plasma anti aging protein klotho in people older than 60 years old, who live in kahrizak old people's home. participants should be non-diabetic, without a history of stroke or Severe cardiovascular disease, without kidney disease and have vitamin D deficiency. 90 participant randomized in 2 groups: receive 50000 IU/d vitamin D weekly and receive placebo weekly.The duration of intervention is 12 weeks. Patient's blood sample is taken before and after the intervention.The questionnaire about personal information, physical activity, recall diet, sun exposure and cognition is completed by experts. Anthropometric measurement include height, weight, waist circumference and blood pressure will be done based on standard

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201511152709N36**
Registration date: **2016-02-18, 1394/11/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-02-18, 1394/11/29

Registrant information

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Recruitment status

Recruitment complete

Funding source

Iran National Science Foundation International Campus of Iran University of medical science

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Supplementation with vitamin D on anti aging protein klotho in old people

Public title

Effects of Supplementation with vitamin D on anti aging protein klotho

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: more than 60 years old; old people with deficiency or insufficiency of serum Vitamin D levels (less than 30ng/ml serum 25-hydroxyvitamin D); Willingness to cooperate in the study; Lack of sensitivity to Vitamin D Supplement; no Consumption of multi vitamin, mineral and omega 3 Supplement; no Consumption of Vitamin D Supplement; Non-diabetic people; Without a history of stroke or Severe card

Age

From **60 years** old

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of medical science
Street address
Iran University of medical science, Hemmat Highway
City
Tehran
Postal code
Approval date
2015-11-18, 1394/08/27
Ethics committee reference number
IR.IUMS.REC.1394.9313680002

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
serum soluble klotho
Timepoint
before and after intervention
Method of measurement
ELISA

2

Description
25(OH)D
Timepoint
before and after intervention
Method of measurement
ELISA

3

Description
1,25(OH)2D
Timepoint
before and after intervention
Method of measurement
ELISA

4

Description
FBS
Timepoint
before and after intervention
Method of measurement
Colorimetric

5

Description
HgA1c
Timepoint
before and after intervention
Method of measurement
Ion exchange

6

Description
hs-CRP
Timepoint
before and after intervention
Method of measurement
ELISA

7

Description
Super Oxide Dismutase assay
Timepoint
before and after intervention
Method of measurement
Calorimetry

8

Description
Cognitive function
Timepoint
before and after intervention
Method of measurement
questionnaire

Secondary outcomes

1

Description
blood pressure
Timepoint
Before and after intervention
Method of measurement
Mercury sphygmomanometer

2

Description
weight
Timepoint
before and after intervention
Method of measurement
Digital scale

3

Description
Dietary intake
Timepoint
before and after intervention
Method of measurement
questionare

4

Description
body mass index
Timepoint
before and after intervention
Method of measurement
Calculation

5

Description
physical activity
Timepoint
before and after intervention
Method of measurement
questionare

6

Description
sun exposure
Timepoint
before and after intervention
Method of measurement
questionare

7

Description
drug consumption
Timepoint
before and after intervention
Method of measurement
questionare

8

Description
Smoking
Timepoint
before and after intervention
Method of measurement
questionare

Intervention groups

1

Description
Intervention group: receive 50000IU vitamin D weekly , for 12 weeks.
Category
Treatment - Other

2

Description
Control group: receive vitamin D placebo weekly , for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kahrizak old people's home
Full name of responsible person
maryam jebreel azimzadeh
Street address
Hakimzadeh Blvd, Kahrizak old people's home, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
International Campus of Iran University of medical science
Full name of responsible person
Doctor Ghasemi
Street address
Iran University of medical science, Hemmat Highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

International Campus of Iran University of medical science

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

Iran University of medical science

Full name of responsible person

Farzad Shidfar

Position

Professor

Other areas of specialty/work

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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