Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Sep 2026

The effect of vitamin k1 supplementation on sensitivity and insulin resistance via osteocalcin in predaibetes patients:A Randomized clinical trial

Protocol summary

Summary

This double blind randomized clinical trial study was designed to investigate the effects of vitamin k1 supplementation on sensitivity and insulin resistance via osteocalcin in prediabetic patients. A total of 84 patients aged 22 to 45 years and 100 ≤FBS≤126, or 140 ≤2hpp≤200mg/dL upon 75 g oral glucose tolerance test (75 g OGTT) who did not receive any medication are selected and randomly allocated into two equal groups of phylloquinone or placebo. The treatment group will receive one 1000 micrograms vitamin K1 as soft gel daily and the placebo group will receive similar soft gel daily as placebo for 4 weeks. Diet and physical activities will be held constant throughout the study. After obtaining the written informed consent, subjects will be assessed regarding dietary intake, anthropometric, clinical and medical history, and biochemical measurements of Carboxylated Osteocalcin(cOCN), Decarboxylated osteocalcin(ucOCN), Total osteocalcin, Leptin, Adiponectin and Glycosylated Haemoglobin(HbA1c)at the beginning and the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120915724N1**
Registration date: **2014-01-08, 1392/10/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-01-08, 1392/10/18

Registrant information

Name

Hamid Rasekhi

Name of organization / entity

Ahvaz jundishapur university of medical science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Ahvaz jundishapur University of Medical Science

Expected recruitment start date

2013-04-09, 1392/01/20

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin k1 supplementation on sensitivity and insulin resistance via osteocalcin in predaibetes patients:A Randomized clinical trial

Public title

The effect of vitamin k1 in diabetic patient treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Willingness to participate in the study and sign the Written informed consent; Age between 22 to 45 years old; BMI=25-29.9 kg/m2; 100 ≤FBS≤126 or

140 ≤2hpp≤200 mg/dL Exclusion criteria: Heart, Kidney, liver and Rheumatoid diseases; Osteoporosis; Hyperthyroidism and Thyroid dysfunction; Pregnancy; Lactation; Menopause; Intake of insulin and glucose and lipid-lowering Agents; Warfarin; Corticosteroids; drugs to treat osteoporosis; Vitamin and Mineral supplements during past 6 months.

Age
From **22 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **84**

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
Ethics Committee of Ahvaz Jundishapur university of medical science, Ahvaz Jundishapur university of

Street address
Vice Chancellor For Research Of Ahvaz Jundishapur University Of Medical Science, Ahvaz, Iran

City
Ahvaz

Postal code

Approval date
2012-11-10, 1391/08/20

Ethics committee reference number
Eth-613

Health conditions studied

1

Description of health condition studied
prediabetes

ICD-10 code
R73.0

ICD-10 code description
Abnormal glucose tolerance test

Primary outcomes

1

Description
Serum carboxylated osteocalcin

Timepoint
Baseline and after 4 weeks

Method of measurement
ELISA assay

2

Description
serum carboxylated osteocalcin

Timepoint
Baseline and after 4 weeks

Method of measurement
ELISA assay

3

Description
serum total osteocalcin

Timepoint
Baseline and after 4 weeks

Method of measurement
ELISA assay

4

Description
serum Hb A1C

Timepoint
Baseline and after 4 weeks

Method of measurement
HPLC assay

5

Description
total energy and nutrient intaake

Timepoint
Baseline, middle and 4th weeks

Method of measurement
24 hour recall

Secondary outcomes

1

Description
fasting and 2 hour serum insulin

Timepoint
Baseline and after 4 weeks

Method of measurement
ELISA assay

2

Description
fasting and 2 hour serum glucose
Timepoint
Baseline and after 4 weeks
Method of measurement
calorimetric assay

3

Description
HOMA-IR
Timepoint
Baseline and after 4 weeks
Method of measurement
formula

4

Description
HOMA-%B
Timepoint
Baseline and after 4 weeks
Method of measurement
formula

5

Description
ISI
Timepoint
Baseline and after 4 weeks
Method of measurement
formula

6

Description
serum adiponectin
Timepoint
Baseline and after 4 weeks
Method of measurement
ELISA assay

7

Description
serum leptin
Timepoint
Baseline and after 4 weeks
Method of measurement
ELISA assay

8

Description
BMI
Timepoint
Baseline and after 4 weeks
Method of measurement
formula

9

Description
waist to hip ratio
Timepoint
Baseline and after 4 weeks
Method of measurement
formula

10

Description
bady fat
Timepoint
Baseline and after 4 weeks
Method of measurement
OMRON

Intervention groups

1

Description
Daily consumption of one 1000 micro grams soft gel vitamin k1 for 4 weeks in intervention group.
Category
Prevention

2

Description
Daily consumption of one softgel placebo for 4 weeks in the control group.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Nutrition Research Center and Metabolic Disease
Full name of responsible person
Dr.Majid Karandish
Street address
Nutrition Research Center and Metabolic Disease, Vice Chancellor For Research Of Ahvaz Jundishapur University Of Medical Science, Ahvaz Jundishapur University Of Medical Science, Ahvaz, Iran
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor For Research Of Ahvaz Jundishapur University Of Medical Science, Ahvaz Jundishapur
Full name of responsible person

Mostafa Feghhi

Street address

Vice Chancellor For Research Of Ahvaz Jundishapur University Of Medical Science, Ahvaz Jundishapur University Of Medical Science, Ahvaz, Iran

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor For Research Of Ahvaz Jundishapur University Of Medical Science, Ahvaz Jundishapur

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

Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Hamid Rasekhi

Position

Ph.D Student

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