

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 $100 \leq \text{FBS} \leq 126$, or $140 \leq 2\text{hpp} \leq 200\text{mg/dL}$ 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

Country

Iran (Islamic Republic of)

Phone

+98 21 4445 1633

Email address

rasekhi.h@ajums.ac.ir

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; $100 \leq \text{FBS} \leq 126$ 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 intake

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 Fegghi

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

Street address

Department of Nutrition, School of ParaMedicine,
Ahvaz Jundishapur University of Medical Sciences,
Ahvaz, Iran

City

Ahvaz

Postal code

Phone

+98 61 1373 8253

Fax

Email

Rasekhi.h@ajums.ac.ir

Web page address

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Ahvaz Jundishapur university of medical science

Full name of responsible person

Majid Karandish

Position

AssociateProfessor

Other areas of specialty/work

Street address

Department of Nutrition, School of ParaMedicine,
Ahvaz Jundishapur University of Medical Sciences,
Ahvaz, Iran

City

Ahvaz

Postal code

Phone

+98 61 1373 8253

Fax

Email

Karandish-m@ajums.ac.ir

Web page address

Person responsible for updating data

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

Street address

Department of Nutrition, School of ParaMedicine,
Ahvaz Jundishapur University of Medical Sciences,
Ahvaz, Iran

City

Ahvaz

Postal code

Phone

+98 61 1373 8253

Fax

Email

Rasekhi.h@ajums.ac.ir

Web page address

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