

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluation the effect of vitamin D on insulin resistance in overweight and obese children with vitamin D deficiency and insulin resistance between age 5 and 15 years old

Protocol summary

Summary

Objective: In this clinical trial the effect of vitamin D supplementation on insulin resistance will be evaluated.
Design: The sample included 62 children 5-15 years old who are obese and overweight presenting to pediatric endocrinology clinic. Design: Within the first visit, Height, weight, BMI, BP, and the maturational status are evaluated. Serum levels of vitamin D, Fasting insulin, 10 hours fasting of lipid profile, Fasting plasma glucose is measured. **Intervention:** In the second phase, patients with insufficient levels of vitamin D or vitamin D deficiency are treated with 50,000 IU of vitamin D Pearl 10 per week to 10 weeks and again, after 2 months from the end of treatment, Serum levels of vitamin D, Fasting plasma glucose and fasting insulin for the effect of vitamin D on insulin resistance will be evaluated. **Participants including major eligibility criteria:** If obesity is due to syndromic disorder or hypothyroidy or patient taking vitamin D the last 6 months are excluded. **Main outcome measures:** Insulin resistance and vitamin D deficiency.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012121811799N1**
Registration date: **2013-05-05, 1392/02/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-05-05, 1392/02/15

Registrant information

Name

Zahra Alian

Name of organization / entity

Sciences Hamedan University of Medical

Country

Iran (Islamic Republic of)

Phone

+98 81 1264 0063

Email address

z.aliان@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Assistant Hamedan University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of vitamin D on insulin resistance in overweight and obese children with vitamin D deficiency and insulin resistance between age 5 and 15 years old

Public title

Effect of vitamin D on insulin resistance

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-All children with overweight and obesity, between the ages of 5 and 15 years 2-No previous treatment with vitamin D. Exclusion criteria: 1-

Obesity with other causes (syndromic disorder, genetic defect, underlying disease) 2- Presence of comorbidities (hypothyroidism, ...) 3- Lack of patient cooperation 4- Previous treatment with vitamin D.

Age

From **5 years** old to **15 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Sciences Hamedan University of Medical, Ethics Committee

Street address

Ethics Committee, School of Medicine, Shahid Fahmide Street

City

Hamedan

Postal code

Approval date

2013-01-01, 1391/10/12

Ethics committee reference number

3489-9-35-16-پ-ر-ر

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E65-E66-E

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Fasting Insulin

Timepoint

Before intervention, 2 Months after the intervention

Method of measurement

ng/dl, ECL method

Secondary outcomes

1

Description

Diabetes

Timepoint

Before intervention, 2 Months after the intervention

Method of measurement

Fasting Blood Sugar, Chyme Enzyme method

2

Description

Obesity

Timepoint

Before intervention, 2 Months after the intervention

Method of measurement

scale, Kg/m²

Intervention groups

1

Description

Pearl vitamin D3, 50000 unit, Manufacturing of Razi Pharmaceutical Company, each week one for 10 week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Endocrinology Clinic

Full name of responsible person

Zahra Alian

Street address

pediatric ward 2, Besat Hospital, Shahid Motahari Blvd.

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Hamedan University of
Medical Sciences

Full name of responsible person

Doctor Heidar Tavilani

Street address

Vice chancellor for research, School of Medicine,
Shahid Fahmide Street

City

Hamedan

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, Hamedan University of
Medical Sciences

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**

School of Medicine, Sciences Hamedan University of
Medical

Full name of responsible person

Zahra Alian

Position

Assistant

Other areas of specialty/work**Street address**

Pediatric ward 2, Besat hospital, Motahari Blvd.

City

Hamedan

Postal code**Phone**

+98 81 1264 0063

Fax**Email**

z_alian@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

School of Medicine, Sciences Hamedan University of
Medical

Full name of responsible person

Zahra Alian

Position

Assistant

Other areas of specialty/work**Street address**

Pediatric ward 2, Besat hospital, Motahari Blvd.

City

Hamedan

Postal code**Phone**

+98 81 1264 0063

Fax

+98 81 1264 0064

Email

z_alian@yahoo.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

School of Medicine, Sciences Hamedan University of
Medical

Full name of responsible person

Zahra Alian

Position

Assistant

Other areas of specialty/work**Street address**

Pediatric ward 2, Besat hospital, Motahari Blvd.

City

Hamedan

Postal code**Phone**

+98 81 1264 0063

Fax**Email**

z_alian@yahoo.com

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