Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Studing the Effect of Vitamin D Deficiency Treatment on Insulin Resistance (Leptin to Adiponectin ratio) in Patients with Diabetes Mellitus

Protocol summary

Summary

Objectives: There exists a growing global concern about the deficiency of vitamin D. Vitamin D deficiency is associated with increased risk for diabetes. Vitamin D improves insulin sensitivity by anti-inflammatory activity. Also vitamin D attenuates expression of pro-inflammatory cytokines involved in insulin resistance (IR) such as interleukin IL-1, IL-6, TNF-a, also down regulates nuclear factor-Kβ activity. Data regarding correction of 25 Hydroxy vitamin D level with insulin resistance in type II diabetic patients are limited. So we aimed to investigate the relationship between treatment of vitamin D deficiency and one of the best correlates of Insulin resistance (Leptin to Adiponectin ratio) in type II diabetic patients. Design: This study is a before/after interventional clinical trial Inclusion criteria: Age more than 18; Vitamin D deficiency(lower than 30 ng/ml) Exclusion criteria: Age more than 70; Severe underlying disease such as Malignancy, End-Stage Renal Disease, Cirrhosis, Connective tissue disease, Congestive Heart Failure; Pregnancy; Autoimmune disease such as Lupus; Acute or chronic infection; Psychiatric diseases under treatment; Recieving Vitamin D supplement during 1 month before study begins. Lastly, fifty patients will enter into the study. Intervention: At baseline and after vitamin D repletion, serum levels of 25 Hydroxy vitamin D, Leptin and Adiponectin will be measured. All patients will be treated by a 50000 Inrernational Unit pearl of vitamin D3 once a week for 8 weeks, followed by 50000 International Unit of vitamin D3 every 2 weeks thereafter for a total of 12 weeks. Main outcome measures (variables): Any relation between Leptin, Adiponectin and Leptin to Adiponectin ratio with improved 25 Hydroxy vitamin D level will be investigated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015070623083N1**
Registration date: **2016-05-15, 1395/02/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-15, 1395/02/26

Registrant information

Name

Haleh Rezaee

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences, East Azerbayjan

Expected recruitment start date

2016-03-01, 1394/12/11

Expected recruitment end date

2017-04-30, 1396/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studing the Effect of Vitamin D Deficiency Treatment on Insulin Resistance (Leptin to Adiponectin ratio) in

Patients with Diabetes Mellitus

Public title
Studing the Effect of Vitamin D Deficiency Treatment on Insulin Resistance
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Age more than 18; Vitamin D deficiency(lower than 30 ng/ml) Exclusion criteria: Age more than 70; Severe underlying disease such as Malignancy, End-Stage Renal Disease, Cirrhosis, Connective tissue disease, Congestive Heart Failure; Pregnancy; Autoimmune disease such as Lupus; Acute or Chronic Infection; Psychiatric diseases under treatment; Recieving Vitamin D supplement during 1 month before study begins.
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
This study is done before and after intervention

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Tabriz University of Medical Sciences
Street address
Number 2 Central Building, Tabriz University of Medical Sciences, International Relations Office, University Street
City
Tabriz
Postal code
5165665931
Approval date
2016-01-18, 1394/10/28
Ethics committee reference number
TBZMED.REC.1394.942

Health conditions studied

1

Description of health condition studied
Diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Leptin level
Timepoint
Baseline and After intervention
Method of measurement
Laboratory methods with Kits

2

Description
Level of vitamin D
Timepoint
Baseline and After intervention
Method of measurement
Laboratory methods with Kits

3

Description
Relation between Leptin, Adiponectin and Leptin to Adiponectin ratio after treating 25Hydroxy Vitamin D levels
Timepoint
After intervention
Method of measurement
Laboratory kits and then divide Leptin level to Adiponectin level

4

Description
Adiponectin level
Timepoint
Baseline and after intervention
Method of measurement
Laboratory methods with Kits

Secondary outcomes

empty

Intervention groups

1

Description
Vitamin D Supplementation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrin Center, Imam Reza Hospital, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Farzad Najafipour
Street address
Opposite side of Central Building of University of Medical Sciences, University Street
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of research, Tabriz University of Medical Sciences
Full name of responsible person
Miss Maleki
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International Relations Office, Number 2 Central Building, Tabriz University of Medical Sciences,University Street
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor of research, Tabriz 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
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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