

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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- α , also down regulates nuclear factor- κ B 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 International 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)

Phone

+98 41 3337 2250

Email address

rezaeeha@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

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

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 intervension

Method of measurement

Laboratory methods with Kits

2

Description

Level of vitamin D

Timepoint

Baseline and After intervension

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 intervension

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

Street address

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

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Haleh Rezaee

Position

Academic member, Assistant Professor of Clinical
Pharmacy

Other areas of specialty/work

Street address

Faculty of Pharmacy, First floor, Department of
Clinical Pharmacy, University Street, Tabriz

City

Tabriz

Postal code

51664-14766

Phone

+98 41 3337 2250

Fax

+98 41 3337 2250

Email

rezaeeha@tbzmed.ac.ir

Web page address

<http://www.tbzmed.ac.ir/>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Haleh Rezaee

Position

PHD of Clinical Pharmacy

Other areas of specialty/work

Street address

Faculty of Pharmacy, First floor, Department of
Clinical Pharmacy, University Street, Tabriz

City

Tabriz

Postal code

51664-14766

Phone

+98 41 3337 2250

Fax

+98 41 3337 2250

Email

Rezaeeha@tbzmed.ac.ir

Web page address

<http://www.tbzmed.ac.ir/>

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Haleh Rezaee

Position

PHD of Clinical Pharmacy

Other areas of specialty/work

Street address

Faculty of Pharmacy, First floor, Department of
Clinical Pharmacy, University Street, Tabriz

City

Tabriz

Postal code

51664-14766

Phone

+98 41 3337 2250

Fax

+98 41 3337 2250

Email

rezaeeha@tbzmed.ac.ir

Web page address

<http://www.tbzmed.ac.ir/>

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