# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The effect of Curcuminoids and Vitamin D3 oral supplementation on Glucagon-like peptide-1, Serum glycemic and lipid profiles, Blood pressure and Body composition in Diabetic Type 2 patients.

## Protocol summary


**Summary**

Objective: Evaluating the effects of Curcuminoids and Vitamin D3 oral supplementation on Glucagon Like Peptide- 1 (GLP- 1) and serum glycemic and lipid profiles, blood pressure and body composition in diabetic type 2 patients; double-blind randomized study; 80 patients will be selected with inclusion and exclusion criteria and will randomly be divided into 4 groups for the 12 weeks of intervention. The first group will receive a Vitamin D3 50,000 IU supplement per week, the second group will receive a supplement that contains 500 milligrams of Curcuminoids per day plus one Vitamin D3 50,000 IU supplement per week, the third group will receive one Curcuminoids supplement daily and The control group will receive a placebo capsule that is similar to Curcuminoids supplements but contains Maltodextrin daily and they also will receive a placebo of Vitamin D3 per week. (each supplement of Curcuminoids contains 500 mg of Turmeric extract that consists of 475 mg Curcuminoids and each capsule of placebo contains 500 mg of Maltodextrin) .


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017041213678N22**
Registration date: **2017-06-08, 1396/03/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2017-06-08, 1396/03/18


**Registrant information**

**Name**

Saeed Ghavamzadeh

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**Recruitment status**

**Recruitment complete**


**Funding source**

Investigator and Vice chancellor for research, Urmia University of Medical Sciences


**Expected recruitment start date**

2016-09-28, 1395/07/07

**Expected recruitment end date**

2016-12-20, 1395/09/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of Curcuminoids and Vitamin D3 oral supplementation on Glucagon-like peptide-1, Serum glycemic and lipid profiles, Blood pressure and Body composition in Diabetic Type 2 patients.

**Public title**

The effect of Curcuminoids and Vitamin D3 oral supplementation on the improvement of glycemia and helping the treatment of Diabetic Type 2 patients.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Subjects diagnosed with Type 2 Diabetes (subjects who are positive for any one of these following criteria: FPG level equal or greater than 126 mg/dL, OGTT at 2 h equal or greater than 200 mg/dL and HbA1c equal or greater than 6.5% or in patients with classic hyperlipidemic signs that their random serum glucose level are equal or greater than 200 mg/dL); older than 18 years old; consumption of Glibenclamide, Metformin, Metformin+ Repaglinide drugs or are under treatment regimen. Exclution criteria; Insulin Therapy and consumption of Sitagliptin, Saxagliptin, Byetta and Victosa drugs; changing in the amount of the drugs for the control of pressure or serum lipids in the past 3 months; Use of herbal medicines and anticoagulants (anti- clotting effects are due to curcuminoids); Change the type and dose of medication during intervention; patients on Dialysis or Hemodialysis (they lack the ability to activate vitamin D in the kidneys); pregnant and lactating women (according to the physiological status of the patients and also different needs for vitamin D); The use of alcohol (low and medium risk of type 2 diabetes is associated with lower risk); People with liver disease (liver plays a key role in the activation of vitamin D); Use of calcium supplements and vitamin D in the last 3 months; People with thyroid disease (due to the fact that thyroid hormones in the regulation of lipids, cholesterol and glucose metabolism play an important role, Therefore it is expected that hypothyroidism is involved in the pathogenesis and progression of diabetes); People who have undergone Cholecystectomy surgery and Gall Bladder stone disease (due to stimulation of curcumin on smooth muscle contraction and stimulate the production of bile); People who use Anti epileptic drugs, Thiazide diuretics, Thyroxine, Digoxin, Corticosteroids, Estrogen, Calcitonin (drugs interfering with the homeostasis of vitamin D); acute gastrointestinal problems (decreased absorption); patients with pancreatic cancer and receiving steroids (secondary causes of hyperglycemia); patients with severe heart disease; People with cancer; People with levels higher than allowed 25- (OH) D, 50ng / ml and higher; People with allergies to turmeric; people who did not eat more than 20 percent of the supplements.

**Age**
From **18 years** old to **75 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **80**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**
Table of randomized numbers, has used to randomize subjects into groups.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Urmia University of Medical Sciences

**Street address**
Orjhans Street, Resalat Blvd, Urmia , Iran

**City**
Urmia

**Postal code**
5714783734

**Approval date**
2016-09-28, 1395/07/07

**Ethics committee reference number**
IR.UMSU.rec.1395.255

## Health conditions studied

### 1

**Description of health condition studied**
Diabetes Mellitus

**ICD-10 code**
E11

**ICD-10 code description**
Non-insulin-dependent diabetes mellitus

## Primary outcomes

### 1

**Description**
Total Cholesterol

**Timepoint**
Before Intervention and 12 weeks after Intervention

**Method of measurement**
Enzymatic method, mg/dl

### 2

**Description**
Fasting Blood Sugar

**Timepoint**
Before Intervention and 12 weeks after Intervention.

**Method of measurement**
Enzymatic method, mg/dl

### 3

**Description**

Triglyceride

**Timepoint**

Before Intervention and 12 weeks after Intervention.

**Method of measurement**

Enzymatic method, mg/dl

**4**

**Description**

LDL Cholesterol

**Timepoint**

Before Intervention and 12 weeks after Intervention.

**Method of measurement**

Enzymatic method, mg/dl

**5**

**Description**

HDL Cholesterol

**Timepoint**

Before Intervention and 12 weeks after Intervention.

**Method of measurement**

Enzymatic method, mg/dl

**6**

**Description**

Hemoglobin A1C

**Timepoint**

Before Intervention and 12 weeks after Intervention.

**Method of measurement**

HPLC method, Percentage

**7**

**Description**

Insulin Resistance

**Timepoint**

Before Intervention and 12 weeks after Intervention.

**Method of measurement**

Fasting Blood Sugar (mg/dl) × Serum Insulin (µu/ml) ÷405

**8**

**Description**

Serum Insulin

**Timepoint**

Before Intervention and 12 weeks after Intervention.

**Method of measurement**

Electro ChemiLuminescence, µU/ml

**9**

**Description**

Fat Mass

**Timepoint**

Before Intervention and 12 weeks after Intervention.

**Method of measurement**

BIA analyzer, Percentage

**10**

**Description**

Fat Free Mass

**Timepoint**

Before Intervention and 12 weeks after Intervention.

**Method of measurement**

BIA analyzer, percentage

**11**

**Description**

Body composition

**Timepoint**

Before intervention and 12 weeks after intervention.

**Method of measurement**

Body composition analyzer (BIA)

**12**

**Description**

Body Mass Index

**Timepoint**

Before Intervention and 12 weeks after Intervention.

**Method of measurement**

BIA, Weight (kg) / [Height (m)]2, kg/m2

**13**

**Description**

Waist to hip circumference

**Timepoint**

Before Intervention and 12 weeks after Intervention.

**Method of measurement**

BIA analyzer, mm

**14**

**Description**

GLP-1( Glucagon Like Peptide-1)

**Timepoint**

Before Intervention and 12 weeks after Intervention

**Method of measurement**

Enzyme Linked Immunosorbent Assay, pmol/l

## Secondary outcomes

**1**

**Description**

Systolic Blood Pressure

**Timepoint**

Before Intervention and 12 weeks after Intervention.

**Method of measurement**

Mercury Sphygmomanometer, mmHg

**2**

**Description**

Diastolic Blood Pressure

**Timepoint**

Before Intervention and 12 weeks after Intervention.

**Method of measurement**

Mercury Sphygmomanometer, mmHg

**3**

**Description**
25 Hydroxy Vitamin D3
**Timepoint**
Before Intervention and 12 weeks after Intervention.
**Method of measurement**
Electro ChemiLuminescence, ngr/ml

## Intervention groups

**1**

**Description**
The first group will receive a Vitamin D3 50,000 IU supplement per week for the period of 12 weeks.
**Category**
Treatment - Other

**2**

**Description**
The second group will receive a supplement that contains 500 milligrams of Curcuminoids per day plus one Vitamin D3 50,000 IU supplement per week for the period of 12 weeks.
**Category**
Treatment - Other

**3**

**Description**
The third group will receive a supplement that contains 500 milligrams of Curcuminoids per day for the period of 12 weeks.
**Category**
Treatment - Other

**4**

**Description**
The control group will receive a placebo capsules that is similar to Curcuminoids supplements but contains Maltodextrin daily and they also will receive a placebo of Vitamin D3 per week for the period of 12 weeks.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Number 2 clinic of Imam Khomeini Hospital
**Full name of responsible person**
Shirin Ebrahimkhani
**Street address**
Number 2 clinic of Imam Khomeini Hospital, Ammar street ,Modarres Blvd ,Urmia
**City**
Urmia

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice chancellor for research, Urmia University of Medical Sciences
**Full name of responsible person**
Dr Iraj Mohebbi
**Street address**
Urmia University of Medical Sciences staffs department, Orjhans Street, Resalat Blvd, Urmia, Iran
**City**
Urmia
**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, Urmia University of Medical Sciences
**Proportion provided by this source**
**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*

**2**

**Sponsor**
**Name of organization / entity**
Student
**Full name of responsible person**
Shirin Ebrahimkhani
**Street address**
Nutrition Department, Faculty of Medicine, Urmia University of Medical Science, 11th km of Nazloo Road, Urmia
**City**
Urmia
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Student
**Proportion provided by this source**
**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**
Urmia University of Medical Sciences
**Full name of responsible person**
Dr Saeed Ghavamzadeh
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**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Other areas of specialty/work**
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**Postal code**
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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*