

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of the rhubarb plant extract compared to placebo on oxidative stress, fasting blood glucose, apolipoprotein B, apolipoprotein A1 and insulin levels in patients with type 2 diabetes

#### Protocol summary

##### Summary

A double-blind study in which the patients and the researchers are not informed of the types of intervention or of the grouping of the patients will be conducted at the Endocrine and Metabolism Research Center and the Diabetes Unit of Shariati Hospital. Only 30-60- year old patients having type 2 diabetes with fasting blood glucose of greater than 126 mg/dl enter the project, and people suffering from hyperglycemia caused by diseases other than diabetes and patients treated with insulin are excluded from it. Sixty patients with type 2 diabetes will be divided randomly (by block randomization) into three 20-member groups receiving aqueous extract of rhubarb, alcoholic extract of rhubarb, or placebo, for 6 weeks. Similar appearance containers each containing 135 drug or placebo capsules with a special code will be delivered to the patients by the therapist of the project and the special code on each container will be recorded in the file of the related patient. Each member of the three groups will receive a container with 135 capsules, with every capsule containing 450 mg of the aqueous extract, of the alcoholic extract, or of the placebo. Each patient will take three capsules every day. The patients in all three groups are tested for the concentrations of malondialdehyde, high sensitivity C-reactive protein, fasting blood glucose, apolipoprotein B, apolipoprotein A-1, and fasting insulin at beginning and at end of the 6th week of study

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201410142709N31**

Registration date: **2014-12-11, 1393/09/20**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-12-11, 1393/09/20

##### Registrant information

###### Name

Farzad Shidfar

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8862 2755

###### Email address

shidfar.f@iums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Iran University of Medical Sciences-Shahid Hemmat Expressway, Central building of Iran University of Medical Sciences

##### Expected recruitment start date

2015-04-04, 1394/01/15

##### Expected recruitment end date

2015-09-06, 1394/06/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the rhubarb plant extract compared to placebo on oxidative stress, fasting blood glucose, apolipoprotein B, apolipoprotein A1 and insulin levels in patients with type 2 diabetes

**Public title**

Effect of rhubarb in diabetes type 2

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: 30-60-year old patients with fasting blood glucose of greater than 126 mg/dl are included in the project. Exclusion criteria: Patients with hyperglycemia caused by diseases other than diabetes, patients suffering from liver, thyroid and kidney diseases, patients being treated with insulin, taking  $\beta$ -blockers and lipid-lowering drugs, consuming alcoholic drinks, having severe, acute, active infectious diseases when blood samples are taken, and patients who are hospitalized during the study are excluded from the study

**Age**

From **30 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features**

Three types of capsules are used in this study: (1) aqueous extract of rhubarb, (2) alcoholic extract of rhubarb, and (3) placebo. The aqueous extract of rhubarb, alcoholic extract of rhubarb, and placebo are as similar capsules with same color and appearance and packaged in similar containers and therefore the patients are not aware of the type of capsules which they take. Also, the researchers are not aware of type of capsules and name of groups. Therefore, this will be a double-blind study.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

**Street address**

The Central Office, Iran University of Medical

sciences, Shahid Hemmat Expressway, between Chamran and Sheikh Fazlollah Expressway

**City**

Tehran

**Postal code****Approval date**

2014-10-12, 1393/07/20

**Ethics committee reference number**

24367

**Health conditions studied****1****Description of health condition studied**

Diabetes type 2

**ICD-10 code**

E10, E11,

**ICD-10 code description**

Insulin-dependent diabetes mellitus, Non-insulin-dependent diabetes mellitus, Malnutrition-related diabetes mellitus, Other specified diabetes mellitus, Unspecified diabetes mellitus

**Primary outcomes****1****Description**

Body Mass Index

**Timepoint**

Before and 6 weeks after intervention

**Method of measurement**

SECA, Kilogram per meter Square

**2****Description**

malondialdehyde

**Timepoint**

Before intervention and 6 weeks after intervention

**Method of measurement**

Spectrophotometry, mmol/L

**3****Description**

High sensitivity c-reactive protein

**Timepoint**

Before and 6 weeks after intervention

**Method of measurement**

immunoturbidimetry, mg/dl

**4****Description**

Fasting Blood Sugar

**Timepoint**

Before and 6 weeks after intervention

**Method of measurement**

glucose oxidase, mg/dl

## 5

### **Description**

Apolipoprotein B

### **Timepoint**

Before and 6 weeks after intervention

### **Method of measurement**

immunoturbidimetry, mg/dl

## 6

### **Description**

Apolipoprotein A1

### **Timepoint**

Before and 6 weeks after intervention

### **Method of measurement**

immunoturbidimetry, mg/dl

## 7

### **Description**

Insulin level

### **Timepoint**

Before and 6 weeks after intervention

### **Method of measurement**

enzymatic, mg/dl

## **Secondary outcomes**

### 1

#### **Description**

Blood Pressure

#### **Timepoint**

Before and 6 weeks after intervention

#### **Method of measurement**

Mercury Sphygmomanometer, mmHg

## **Intervention groups**

### 1

#### **Description**

Intervention group 1: Every day, members of the intervention group 1 receive three 450 mg oral capsules of the aqueous extract of rhubarb for six weeks which is made at School of Pharmacy, Shahid Beheshti University of Medical Sciences.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

control group: Every day, members of the control group receive three 450 mg oral capsules of the placebo for six weeks which is made at School of Pharmacy, Shahid Beheshti University of Medical Sciences.

#### **Category**

Placebo

## 3

### **Description**

Intervention group 2: Every day, members of the intervention group 1 receive three 450 mg oral capsules of the alcoholic extract of rhubarb for six weeks which is made at School of Pharmacy, Shahid Beheshti University of Medical Sciences.

### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shariati Hospital, Tehran

##### **Full name of responsible person**

##### **Street address**

##### **City**

Tehran

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice Chancellor for research, Iran University of Medical Sciences,

##### **Full name of responsible person**

Dr. Seyed Ali Javad Mousavii- Vice Chancellor for research, Iran University of Medical Sciences

##### **Street address**

5th floor, the Office of the Vice Chancellor for research, the Central Office, Iran University of Medical Sciences, Shahid Hemmat Expressway, between Chamran and Sheikh Fazlollah Expressway

##### **City**

Tehran

##### **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, Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Farzad Shidfar

**Position**

Ph.D- Faculty member of Iran University of Medical Sciences

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

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Web page address**

## Person responsible for updating data

### Contact

## 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*