

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Evaluation of Rheum ribes L. aqueous extract effect on depression in type2 diabetic patients

#### Protocol summary

##### Summary

This was an experimental double blind randomized controlled trial (RCT) to evaluate the Rheum ribes L. aqueous extract effect on depression in type2 diabetic patients referring to Yazd Diabetes Research Center. Fifty four patients (40-70 years old) with at least two years of diabetes history and Hb A1c  $\leq 10$  but not suffering from other mental diseases under treatment (schizophrenia, obsession compulsive disorder, anxiety), chronic diseases (heart failure, cancer, respiratory failure), chronic kidney and chronic liver diseases and depressed patients admitted to the hospital were selected and assigned into two groups randomly. Randomized block method was used to make assignment random. The intervention group received required medications and 1200 mg aqueous extract of rhubarb daily for six weeks. In the control group patients received required medications and placebo. In each group, Patients were evaluated before the intervention and at the end of the 4th and 6th week by the Hamilton Rating Scale for Depression (HAM-D) and these results were compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017041018828N3**

Registration date: **2017-04-24, 1396/02/04**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-04-24, 1396/02/04

##### Registrant information

**Name**

Alimohammad Ranjbar

##### Name of organization / entity

Yazd University of Medical Sciences

##### Country

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##### Phone

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##### Recruitment status

**Recruitment complete**

##### Funding source

Yazd University of Medical Sciences

##### Expected recruitment start date

2017-04-21, 1396/02/01

##### Expected recruitment end date

2017-06-22, 1396/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Rheum ribes L. aqueous extract effect on depression in type2 diabetic patients

##### Public title

Evaluation of Rheum ribes L. aqueous extract effect on depression

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: aged 40 to 70 years; with at least 2 years of being diabetes patient; HbA1c  $< 10\%$  exclusion criteria: suffering from other mental diseases under treatment; chronic disease (heart failure, cancer, chronic kidney and chronic liver disease); hospitalized patients with depression ; allergy to Rheum ribes L. aqueous

**Age**

From **40 years** old to **70 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **54**

**Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Yazd University of Medical Sciences

**Street address**

Bahonar square, Yazd, Iran

**City**

Yazd

**Postal code**

8917693571

**Approval date**

2016-08-14, 1395/05/24

**Ethics committee reference number**

IR.SSU.REC. 1395.66

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

Type 2 diabete

**ICD-10 code**

E10, E11,

**ICD-10 code description**

Diabetes mellitus

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

Depression

**Timepoint**

Before the intervention, The end of the fourth week, The end of the Sixth week

**Method of measurement**

Hamilton Rating Scale for Depression

**Secondary outcomes****1****Description**

HbA1C

**Timepoint**

Before the intervention, After intervention

**Method of measurement**

Blood Test

**Intervention groups****1****Description**

The intervention group received required medications and 1200 mg aqueous extract of rhubarb daily for six weeks.

**Category**

Treatment - Drugs

**2****Description**

In the control group patients received required medications and placebo

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Yazd Diabete Research Center

**Full name of responsible person**

Masoud Rahmanian

**Street address**

Talar Honar alley, Bahonar square, Yazd, Iran

**City**

Yazd

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Yazd University of Medical Sciences

**Full name of responsible person**

Hooshang Mehrparvar

**Street address**

Bahonar Square, Yazd, Iran

**City**

Yazd

**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 of Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

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PhD

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Diabete Research Center

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Student Doctor of Pharmacy

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**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*