

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

To evaluate the efficacy and side effects of using the combination of Trigonella foenum-graecum L and Citrullus colocynthis (L.) (Diabetic Capsule) in treatment of diabetic patients as a complementary therapy

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

To evaluate the efficacy and side effects of using the combination of Trigonella foenum-graecum L and Citrullus colocynthis (L.) (Diabetic Capsule) in treatment of diabetic patients as a complementary therapy

Last update: **2018-04-16, 1397/01/27**

Update count: **0**

Registration date

2018-04-16, 1397/01/27

Design

Randomized controlled clinical trial with parallel groups and triple blinded.

Registrant information

Name

Massih Sedigh Rahimabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3825 6275

Email address

sedighrm@sums.ac.ir

Settings and conduct

This study is conducting in Fasa and participants, researchers and analyzer are blinded to the study groups.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

All the diabetic patients with HgbA1c more than 6.4 who are between 30 to 65 years old and have a weight 55 to 100 kg will recruit in this study. Additional inclusion criteria are; not to have any alcohol or drug addiction, have a BMI between 24 to 35 and not to consume any cortone and herbal or chemical anti-diabetic drug.

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-08-21, 1397/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

For 3 months, in drug group; addition to conventional anti-diabetic drugs, capsules with 40 mg Citrullus colocynthis and 350 mg Trigonella foenum-graecum are administrated 2 times per day. And in control group; addition to conventional anti-diabetic drugs, capsules with 350 mg corn flour are administrated 2 times per day.

Main outcome variables

FBS; BS2pp; HgbA1c; Cholestrol; HDL; LDL; TG and LFT

Scientific title

To evaluate the efficacy and side effects of using the combination of Trigonella foenum-graecum L and Citrullus colocynthis (L.) (Diabetic Capsule) in treatment of diabetic patients as a complementary therapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140715018490N3**

Registration date: **2018-04-16, 1397/01/27**

Public title

To evaluate Fenugreek and Bitter apple in treatment of diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of diabetes (FBS>126 mg/dl) To have a FBS less than 250 and HgbA1c more than 6.4 Age between 30 to 65 Not to have any additional systemic diseases like; liver, renal, rheumatologic diseases or hypertension Not to consume any anti-diabetic or corticosteroid drugs 2 weeks before the study Not to drink alcohol or use opium To have a weight between 55-100 To have a BMI between 24 to 35

Exclusion criteria:

Not agree to participate in the study. To have a FBS more than 270 mg/dl Consuming corticosteroid drugs during the study Presence of any side effects

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **74**

More than 1 sample in each individual

Number of samples in each individual: **3**

Venous blood (10 cc) for lab data

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked Randomized Table

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, researchers and data analyzer were blinded to the study groups. We made the placebo and therapeutic capsules like each other and labeled them by a letter -from A to D.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Comimitte of Fasa University of Medical Sciences

Street address

Ebn-Sina square

City

Fasa

Province

Fars

Postal code

86688-74616

Approval date

2017-09-05, 1396/06/14

Ethics committee reference number

IR.FUMS.REC.1396.219

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

FBS

Timepoint

At the beginning of intervention, after 2 weeks then after 12 weeks from the beginning of intervention

Method of measurement

Blood sampling

2

Description

HgbA1C

Timepoint

At the beginning of intervention and after 12 weeks from the beginning of intervention

Method of measurement

Blood sampling

3

Description

Total cholesterol

Timepoint

At the beginning of intervention and after 12 weeks from the beginning of intervention

Method of measurement

Blood sampling

4

Description

BS2pp

Timepoint

At the beginning of intervention, after 2 weeks then after 12 weeks from the beginning of intervention

Method of measurement

Blood sampling

5

Description

LDL

Timepoint

At the beginning of intervention and after 12 weeks from the beginning of intervention

Method of measurement

Blood sampling

6

Description

HDL

Timepoint

At the beginning of intervention and after 12 weeks from the beginning of intervention

Method of measurement

Blood sampling

7

Description

SGOT

Timepoint

At the beginning of intervention and after 12 weeks from the beginning of intervention

Method of measurement

Blood sampling

8

Description

SGPT

Timepoint

At the beginning of intervention and after 12 weeks from the beginning of intervention

Method of measurement

Blood sampling

9

Description

Alp

Timepoint

At the beginning of intervention and after 12 weeks from the beginning of intervention

Method of measurement

Blood sampling

10

Description

TG

Timepoint

At the beginning of intervention and after 12 weeks from the beginning of intervention

Method of measurement

Blood sampling

Secondary outcomes

1

Description

Satisfaction of patients

Timepoint

3 months after recruitment

Method of measurement

visual analog scale

2

Description

Tolerance

Timepoint

3 months after recruitment

Method of measurement

visual analog scale

3

Description

Temperament

Timepoint

At the beginning of the study

Method of measurement

Questionnaire

4

Description

Drug side effects

Timepoint

3 months after recruitment

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: Addition to conventional anti-diabetic drugs, capsules with 40 mg Citrullus colocynthis and 350 mg Trigonella foenum-graecum are administrated 2 times per day for 3 months.

Category

Treatment - Drugs

2

Description

Control group: In this group; addition to conventional anti-diabetic drugs, capsules with 350 mg corn flour are administrated 2 times per day for 3 months.

Category

Placebo

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

Diabetes Clinic

Full name of responsible person

Fatemeh Kerdegari

Street address

Taleghani

City

Fasa

Province

Fars

Postal code

12

Phone

+98 71 5331 4076

Email

f.kerdegari@gmail.com

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

Fasa University of Medical Sciences

Full name of responsible person

Dr. Mojtaba Farjam

Street addressFasa University of Medical Sciences, Ebnesina square,
Fasa**City**

fasa

Province

Fars

Postal code

7461686688

Phone

+98 71 5335 0994

Email

akrami_e@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Fasa University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Fasa University of Medical Sciences

Full name of responsible person

Massih Sedigh Rahimabadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Ghazal II, Paez st., Pasargad Ave.

City

Shiraz

Province

Fars

Postal code

123456789

Phone

+98 71 3825 6275

Fax

+98 71 1230 9979

Email

sedighrm@sums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Fasa University of Medical Sciences

Full name of responsible person

Massih Sedigh Rahimabadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Ghazal II, Paez st., Pasargad Ave.

City

Shiraz

Province

Fars

Postal code

123456789

Phone

+98 71 3825 6275

Fax

+98 71 1230 9979

Email

sedighrm@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Fasa University of Medical Sciences

Full name of responsible person

Massih Sedigh Rahimabadi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

Street address

Ghazal II, Paez st., Pasargad Ave.

City

Shiraz

Province

Fars

Postal code

123456789

Phone

+98 71 3825 6275

Fax

+98 71 1230 9979

Email

sedighrm@sums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data and results of analysis will be published in a paper.

When the data will become available and for how long

After the end of study.

To whom data/document is available

All of those who have access to the article.

Under which criteria data/document could be used

The editor in chief, if necessary.

From where data/document is obtainable

Vice chancellor for research affair of Fasa University of Medical Sciences

What processes are involved for a request to access data/document

Asking from Vice chancellor for research affair of Fasa University of Medical Sciences

Comments