Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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

Design
Randomized controlled clinical trial with parallel groups and triple blinded.

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

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.

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140715018490N3**
Registration date: **2018-04-16, 1397/01/27**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-16, 1397/01/27**
Update count: **0**

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

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

Recruitment status
Recruitment complete

Funding source

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

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

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 Comimtte 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 address
Fasa 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, Paeez 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, Paeez 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, Paeez 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