Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jun 2026

To evaluate the efficacy and side effects of using the Ma-al-Jobn in treatment of diabetic type II patients as a complementary therapy

Protocol summary

Study aim
To evaluate the efficacy and side effects of using the Ma-al-Jobn (whey protein) in treatment of diabetic patients as a complementary therapy

Design
Randomized controlled clinical trial with parallel groups and double blinded

Settings and conduct
This study is conducting in Fasa and participants and researchers 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 less than 100 kg will recruit in this study. Additional inclusion criteria are; not to have any alcohol or drug addiction, have a BMI less than 35 and not to consume any corticosteroid and herbal or chemical anti-diabetic drug.

Intervention groups
Participants consume a sachet per day for 3 months besides their anti-diabetic drugs. They open a sachet in a glass of hot water (150-200 cc) and drink it before breakfast. In drug group each sachet contains whey protein and in control group each sachet has caramelized corn flour.

Main outcome variables
FBS; BS2pp; HgbA1c; Cholestrol; HDL; LDL; TG and LFT

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140715018490N4**
Registration date: **2018-07-20, 1397/04/29**
Registration timing: **prospective**

Last update: **2018-07-20, 1397/04/29**
Update count: **0**

Registration date
2018-07-20, 1397/04/29

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
2018-07-23, 1397/05/01

Expected recruitment end date
2019-02-20, 1397/12/01

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 Ma-al-Jobn in treatment of diabetic type II patients as a complementary therapy

Public title
To evaluate the complementary effect of whey protein for treatment of diabetes type II

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Presence of diabetes (FBS>126 mg/dl) Have a FBS less

than 250 and HgbA1c more than 6.4 Age between 30 to 65 years No systemic diseases like; liver, renal, rheumatologic diseases or hypertension No consume any anti-diabetic or corticosteroid drugs 2 weeks before the study No drink alcohol or use opium Weight less than 100 kg Have a BMI less than 35

Exclusion criteria:

No agree to participate in the study 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
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked Randomized Table

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and researchers are blinded to the study groups. Placebo and therapeutic sachets are similar to each other and labeled by a letter (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

2018-03-13, 1396/12/22

Ethics committee reference number

IR.FUMS.REC.1396.313

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

Venous blood sampling

2

Description

HgbA1C

Timepoint

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

Method of measurement

Venous blood sampling

3

Description

Total cholesterol

Timepoint

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

Method of measurement

Venous 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

Venous blood sampling

5

Description

LDL

Timepoint

At the beginning of intervention and after 12 weeks from

the beginning of intervention

Method of measurement

Venous blood sampling

6

Description

HDL

Timepoint

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

Method of measurement

Venous blood sampling

7

Description

SGOT

Timepoint

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

Method of measurement

Venous blood sampling

8

Description

SGPT

Timepoint

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

Method of measurement

Venous blood sampling

9

Description

Alp

Timepoint

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

Method of measurement

Venous blood sampling

10

Description

TG

Timepoint

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

Method of measurement

Venous 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

Drug group: In addition to anti-diabetes medications, patients in this group should receive a sachet of whey protein powder (12.5 g. each) in 150-200 cc of hot water every day. They are asked to drink it before breakfast and not to eat or drink until 1 hour after consumption.

Category

Treatment - Drugs

2

Description

Control group: In addition to anti-diabetes medications, patients in this group should receive a sachet of caramelized corn powder (5 g. each) in 150-200 cc of hot water every day. They are asked to drink it before breakfast and not to eat or drink until 1 hour after consumption.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic

Full name of responsible person

Sahar Sajadi
Street address
Taleghani st.
City
Fasa
Province
Fars
Postal code
12
Phone
+98 71 5331 4076
Email
massih21@yahoo.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
pajohan@fums.ac.ir
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
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Person responsible for scientific inquiries

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Position
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Other areas of specialty/work
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City
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123456789
Phone
+98 71 3825 6275
Email
massih21@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Sahar Sajadi
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
Anesthesiology
Street address
Fasa university of medical sciences, Ibn-e-Sina Sq.
City

Fasa

Province

Fars

Postal code

74616-86688

Phone

+98 71 5331 4076

Email

saharsajjadi1396@gmail.com

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