

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

To evaluate the complementary efficacy of a compound herbal drug (Thymus daenensis, Matricaria chamomilla L. , Achillea santolina & Satureja bachtiarica Bunge) in patients with diabetes type II

Protocol summary

Study aim

To evaluate the efficacy and side effects of using the combination of herbal drug (Thymus daenensis, Matricaria chamomilla L. , Achillea santolina & Satureja bachtiarica Bunge) (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 Shiraz and participants, researchers and analyzer are blinded to the study groups

Participants/Inclusion and exclusion criteria

En 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 18 to 35 and not to consume any cortone and herbal or chemical anti-diabetic drug.

Intervention groups

This study has 2 drug and 1 control groups. In drug groups; for three months, in addition to the common anti-diabetic drugs: either type 1 capsules of diabetes (each capsule contains aqueous extract of 100 mg of thyme, 100 mg of chamomile, 200 mg of Achillea and 100 mg of Satureja), or type 2 diabetes capsules (Each capsule contains dried hydro-alcoholic extracts of 100 mg Thymus, 100 mg chamomile, 200 mg of Achillea officinalis and 100 mg of Satureja) are prescribed, and to the control group instead of the capsule of diabetes, placebo capsules which contain 500 mg of corn flour are given.

Main outcome variables

FBS; BS2pp; HgbA1c; Cholestrol; HDL; LDL; TG; LFT and gene expression of: PPARy, IGFBP-2, IGFR, IGF-1 and IR.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140715018490N6**

Registration date: **2018-11-13, 1397/08/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-13, 1397/08/22**

Update count: **0**

Registration date

2018-11-13, 1397/08/22

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

2018-08-06, 1397/05/15

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To evaluate the complementary efficacy of a compound herbal drug (Thymus daenensis, Matricaria chamomilla L., Achillea santolina & Satureja bachtiarica Bunge) in patients with diabetes type II

Public title

Effect of compounds (Thymus daenensis, Matricaria chamomilla L., Achillea santolina & Satureja bachtiarica Bunge) on the treatment of diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Presence of diabetes (FBS>126 mg/dl) To have a FBS less than 270 and HgbA1c more than 5.6 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 18 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: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

A random table with blocks of 6. In this method; using an existing electronic software such as "https://www.sealedenvelope.com/simple-randomiser/v1/lists", we create a randomized list of 6 blocks for the 3 study groups. In this list, letters A, B, and C as three groups of this study are randomly distributed in groups of 6. And on the basis of this list, medications are given to the patients respectively.

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 C.

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

2639-01-21, 2017/11/01

Ethics committee reference number

IR.FUMS.REC.1396.296

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

FBS

Timepoint

At the beginning of intervention, after 4 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

كلسترول تام

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 4 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

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

Alp

Timepoint

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

Method of measurement

Venous blood sampling

9

Description

TG

Timepoint

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

Method of measurement

Venous blood sampling

10

Description

SGPT

Timepoint

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

Method of measurement

Venous blood sampling

11

Description

PPARγ1 gene expression

Timepoint

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

Method of measurement

Venous blood sampling

12

Description

IGFBP-2 gene expression

Timepoint

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

Method of measurement

Venous blood sampling

13

Description

IGFR gene expression

Timepoint

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

Method of measurement

Venous blood sampling

14

Description

IGF-1 gene expression

Timepoint

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

Method of measurement

Venous blood sampling

15

Description

IR gene expression

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

Intervention group 1: In addition to anti diabetic drugs, a coded bottle containing type 1 diabetic capsules (each capsule containing dried aqueous extract of 100 mg of Thymus, 100 mg of chamomile, 200 mg of Achillea and 100 Mg Satureja), is given to the patients. This means that: besides their anti diabetic drugs, they should consume 2 other capsules per day (one in the morning and one in the evening) for 3 months.

Category

Treatment - Drugs

2

Description

Intervention group 2: In addition to anti diabetic drugs, a coded bottle containing type 2 diabetic capsules (each

capsule containing dried hydro-alcoholic extract of 100 mg of Thymus, 100 mg of chamomile, 200 mg of Achillea and 100 Mg Satureja), is given to the patients. This means that: besides their anti diabetic drugs, they should consume 2 other capsules per day (one in the morning and one in the evening) for 3 months.

Category

Treatment - Drugs

3

Description

Control group: In addition to anti diabetic drugs, a coded bottle containing placebo capsules (each capsule containing 500 mg of caramelized corn flour), is given to the patients. This means that: besides their anti diabetic drugs, they should consume 2 other capsules per day (one in the morning and one in the evening) for 3 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Traditional Persian Clinic

Full name of responsible person

Jamshidi Neda

Street address

Felestin st.

City

Shiraz

Province

Fars

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1111111111

Phone

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Email

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2

Recruitment center

Name of recruitment center

Doctor Forough Pour's office

Full name of responsible person

Doctor Forough Pour

Street address

golzar

City

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Province

Fars

Postal code

22222222

Phone

+98 71 3620 5451

Email

n.jamshidi69@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

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Province

Fars

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7461686688

Phone

+98 71 5335 0994

Email

research@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

Neda Jamshidi Gorki

Position

Student

Latest degree

Master

Other areas of specialty/work

Biochemistry

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Person responsible for scientific inquiries

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Full name of responsible person

Massih Sedigh Rahimabadi

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Assistant professor

Latest degree

Ph.D.

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Person responsible for updating data

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Full name of responsible person

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Latest degree

Master

Other areas of specialty/work

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Phone

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Email

n.jamshidi69@gmail.com

Web page address

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