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: PPARγ, 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)
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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 Comimtte 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
کلسترول 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, after4 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
PPARγI 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
Postal code
1111111111
Phone
+98 71 3234 0461
Email
n.jamshidi69@gmail.com

2

Recruitment center
Name of recruitment center
Doctor Forough Pour's office
Full name of responsible person
Doctor Forough Pour
Street address
golzar
City
shiraz
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
City
Fasa
Province
Fars
Postal code
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
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Latest degree
Ph.D.
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Person responsible for updating data

Contact
Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Neda Jamshidi Goraki
Position
student
Latest degree
Master
Other areas of specialty/work
Biochemistry
Street address
No. 10, 4th alley, Reis-ali Delvar street, Shahrak Golestan
City
shiraz
Province
Fars
Postal code
7189935335
Phone
+98 71 3620 5451
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