Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Anti-diabetic effect of herbal formulation versus placebo in diabetic patients: a triple-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of herbal formulation versus placebo in diabetic patients
Design
This is a triple-blind randomized clinical trial, phase II, in which 58 eligible patients will be randomly assigned to the intervention and control groups
Settings and conduct
The eligible diabetic patients who will refer to Shahid Beheshti Hospital during the study period will be enrolled in the trial
Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 30 to 60 years; Type 2 diabetes; Hemoglobin A1c above 7% Exclusion criteria: Renal disorder; Liver disorder; Gastric disorder; Cardiovascular diseases
Intervention groups
Intervention group: Routine treatment of diabetes plus herbal formulation capsule 100 mg daily for 3 months Control group: Routine treatment of diabetes plus placebo capsule daily for 3 months
Main outcome variables
Primary outcome: Measuring fasting blood sugar Measuring blood sugar Measuring hemoglobin A1c

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20120215009014N229**
Registration date: **2018-08-22, 1397/05/31**
Registration timing: **prospective**

Last update: **2018-08-22, 1397/05/31**
Update count: **0**
Registration date
2018-08-22, 1397/05/31

Registrant information
Name
Jalal Poorolajal
Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-09-23, 1397/07/01
Expected recruitment end date
2019-09-23, 1398/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Anti-diabetic effect of herbal formulation versus placebo in diabetic patients: a triple-blind randomized clinical trial

Public title
Anti-diabetic effect of herbal formulation versus placebo in diabetic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 30 to 60 years; Type 2 diabetes; Hemoglobin A1c above 7%
Exclusion criteria:

Renal disorder; Liver disorder; Gastric disorder; Cardiovascular diseases

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions Therefore, the trial will be run as triple blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-07-21, 1397/04/30

Ethics committee reference number

IR.UMSHA.REC.1397.299

Health conditions studied

1

Description of health condition studied

Diabetes mellitus

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Measuring fasting blood sugar

Timepoint

Before intervention and 3 and 6 months after intervention

Method of measurement

By laboratory test

2

Description

Measuring blood sugar

Timepoint

Before intervention and 3 and 6 months after intervention

Method of measurement

By laboratory test

3

Description

Measuring hemoglobin A1c

Timepoint

Before intervention and 3 and 6 months after intervention

Method of measurement

By laboratory test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine treatment of diabetes plus herbal formulation capsule 100 mg daily for 3 months

Category

Treatment - Drugs

2

Description

Control group: Routine treatment of diabetes plus placebo capsule daily for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Mohammad Amin Shakeri Rad

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School of Pharmacy, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mohammad Amin Shakeri Rad

Position

Pharmacology Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Professor of Epidemiology

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Epidemiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available