

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

#### 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

IR.UMSHA.REC.1397.299

## 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

## 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

**Street address**

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

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shakeri.amin.kourosh@gmail.com

**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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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

**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**

**Contact**

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Hamedan University of Medical Sciences

**Full name of responsible person**

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**Position**

Pharmacologist

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

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## Person responsible for updating data

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### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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