

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of nutritional management in view of Iranian traditional medicine on HbA1c in type 2 diabetics referred to yazd diabete centre

Protocol summary

Summary

The purpose of this study is determining the impact of nutritional style of traditional medicine on HbA1c of type 2 diabetic patients referred to Yazd Diabetes Centre. Type of this study is Randomized Controlled Clinical Trial(RCCT). Inclusion criteria: definite diagnosis of diabetes mellitus that affirmed with Fbs>126 in twice & the specialist confirmed it; their hba1c will be between 7.5 to 9.5; they want and could cooperate in study ; they should not have pregnancy or lactation ,malignancy and Alzheimer ; they should not have any complication of Diabetes mellitus, like cardiovascular or renal disorders. Exclusion criteria: patient un cooperate within study ; wont come at determined time ;because of increasing level of blood glucose need to intervention ;unpredictable problem that interact with study sample volume is 26 persons in each group. initial HbA1c of all patients will be evaluated and recorded at first . the nutritional style of traditional medicine will be taught to The intervention group. HbA1c of both groups should be evaluated and recorded after 3 months of follow up, then results will be compared with the first

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080129150N1**

Registration date: **2016-08-15, 1395/05/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-15, 1395/05/25

Registrant information

Name

Seyedkazem Kazemeini

Name of organization / entity

Yazd Shahid sadooghi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 353740171

Email address

sk.kazemeini@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Funding was provided By Yazd Shahid sadooghi University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of nutritional management in view of Iranian traditional medicine on HbA1c in type 2 diabetics referred to yazd diabete centre

Public title

Effect of traditional medicine nutritional style on diabetes mellitus

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: definite diagnosis of diabetes mellitus that affirmed with FBS>126 in twice & the specialist confirmed it; their hba1c will be between 7.5 to 9.5; they want and could cooperate in study ; they should not have

pregnancy or lactation ,malignancy and Alzheimer ; they should not have any complication of Diabetes mellitus, like cardiovascular or renal disorders. Exclusion criteria: patient un cooperate within study ; wont come at determined time ;because of increasing level of blood glucose need to intervention ;unpredictable problem that interact with study

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yazd Shahid Sadooghi Univesity of Medical Sciences

Street address

Bahonar Squire

City

Yazd

Postal code

Approval date

2015-11-30, 1394/09/09

Ethics committee reference number

IR.SSU.REC.1394.120

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E12

ICD-10 code description

Malnutrition-related diabetes mellitus

Primary outcomes

1

Description

HbA1c

Timepoint

3 month

Method of measurement

HbA1c lab test

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Patients in the intervention group feeding correct method based on traditional medicine are taught face to face and then checked before and after the three-month period

Category

Lifestyle

2

Description

In the control group of patients will be asked to continue with the previous method of feeding your doctor and Hba1c be examined at the beginning and end of the 3 month period

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabete Center

Full name of responsible person

Seyedkazem Kazemeini

Street address

Bahonar squire. Shahidsadooghi Ave

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd Shahidsadooghi University of Medical Sciences

Full name of responsible person

Amirhooshang Mehrparvar

Street address

Bahonar Square

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd Shahidsadooghi University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Traditional Medicine Faculty of Ardakan

Full name of responsible person

Seysdkazem Kazemeini

Position

Student (ph.D candidate)

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty