Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jan 2021

The effect of Caraway powder consumption on glycemic indices, lipid profile and Serum levels of nesfatin-1 in overweight and obese patients with type 2 diabetes

Protocol summary

Study aim

The effect of Caraway powder consumption on glycemic indices , lipid profile and nesfatin-1 in type 2 diabetic patients

Design

Clinical trial with intervention and control group, with parallel groups,double blind, randomized,

Settings and conduct

48 patients with type 2 diabetes who referred to Diabetes Clinic of Booali Hospital in Zahedan who were eligible to enter the study will be selected. The samples were randomly assigned to two intervention groups (n=24) and control group (n = 24). The intervention group received 2 grams of caraway powder (2 , 1 gram capsules) per day (1 capsule with lunch and dinner) and placebo control (starch) daily. All Participants in the project thought that they had received intervention and they do not know were in the group receiving the caraway powder or the placebo group. Also, the medical staff and secretaries that provide the capsules to the patients are unaware of the contents of the capsules.

Participants/Inclusion and exclusion criteria

Patients with type 2 diabetes referred to the diabetes clinic of Booali Hospital in Zahedan in 1397 Inclusion criteria: 1.Body mass index 25 to 40 2.People 30 to 65 years old 3. having a fasting blood glucose level of 126 to 250 mg / dL 4.Use of oral hypoglycemic drugs exclusion criteria: 1.Pregnancy and lactation 2.chronic diseases (hypertension,heart ,kidney and liver diseases, hypothyroidism, systemic infection) 3. Caraway Hypersensitivity

Intervention groups

The intervention group received 2 grams of Caraway powder daily, approved by Faculty of Pharmacy, Kerman University of Medical Sciences (2 ,1 gram capsules) 2 servings per day (1 capsule with lunch and dinner) for 8 weeks, and the control group received 2 grams Starch from Shiraz Momtaz Factory (2, 1 g capsules) in 2 servings per day (1 capsule with lunch and dinner) for 8 weeks.

Main outcome variables

nesfatin-1; Fasting blood sugar; Lipid profile

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181207041876N1**
Registration date: **2019-01-18, 1397/10/28**
Registration timing: **prospective**

Last update: **2019-01-18, 1397/10/28**
Update count: **0**

Registration date

2019-01-18, 1397/10/28

Registrant information

Name

saber jafari maskoni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4335 0154

Email address

saberjafarimaskouni@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Caraway powder consumption on glycemic indices, lipid profile and Serum levels of nesfatin-1 in overweight and obese patients with type 2 diabetes

Public title
Effect of Caraway Powder consumption on the Treatment of Type 2 Diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
given diabetes and having a fasting blood suger level of 126 to 250 mg / dL Consumption of oral glucose-lowering medicines Age range of 30 to 65 years Body mass index 25 to 40
Exclusion criteria:
given Chronic diseases (high blood pressure, heart, kidney, hypothyroidism, liver, systemic infection) Pregnancy and lactation Hypersensitivity to Caraway
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
For randomization,permuted block randomization will be used with Fourth blocks. According to the 48-sampled sample size, 12 Fourth block will be produced using the online site (www.sealedenvelope.com).
Blinding (investigator's opinion)
Double blinded
Blinding description
All capsules given to participants in the intervention and placebo groups are same size and color, and all of the participants will not be informed about difference between the Caraway and placebo capsules. This is performed by a non-researcher person such as Nurses or treatment staff and will not be informed about difference between the Caraway and placebo capsules.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zahedan University of Medical Sciences
Street address
Daneshgah Blvd- Dr. Hassabi Square- Baluchestan Blvd.
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816737789
Approval date
2018-12-02, 1397/09/11
Ethics committee reference number
IR.ZAUMS.REC.1397.332

Health conditions studied

1

Description of health condition studied
type 2 diabetes
ICD-10 code
E11.9
ICD-10 code description
Type 2 diabetes mellitus without complications

Primary outcomes

1

Description
Fasting Blood Suger
Timepoint
One day before intervention and one day after end of intervention
Method of measurement
Enzymatic method using kits

2

Description
Nesfatin-1
Timepoint
One day before intervention and one day after intervention
Method of measurement
Enzymatic method using ELISA kit

3

Description

triglycerides

Timepoint

One day before intervention and one day after intervention

Method of measurement

Enzymatic method using kits

4

Description

Fasting Blood insulin

Timepoint

One day before intervention and one day after intervention

Method of measurement

Enzymatic method using ELISA kit

5

Description

Insulin resistance

Timepoint

One day before intervention and one day after intervention

Method of measurement

The product of fasting glucose concentration in fasting insulin concentration divided by constant number 22.5

6

Description

High density lipoprotein

Timepoint

One day before intervention and one day after intervention

Method of measurement

Enzymatic method using kits

7

Description

Low density lipoprotein

Timepoint

One day before intervention and one day after intervention

Method of measurement

Enzymatic method using kits

8

Description

Total cholesterol

Timepoint

One day before intervention and one day after intervention

Method of measurement

Enzymatic method using kits

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group consumes 2 grams of Caraway powder capsules (one gram capsule after lunch and one gram capsule after a dinner) approved by the College of Pharmacy, Kerman University of Medical Sciences for 8 weeks.

Category

Treatment - Other

2

Description

The control group consumes 2 grams of starch capsules (one gram capsule after lunch and one gram capsule after a dinner) Of Shiraz Momtaz Starch Company for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Buali Hospital in Zahedan

Full name of responsible person

Saber Jafari Maskoni

Street address

Bu'ali Hospital ,Daneshgah Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Noor Mohammad Bakhshani

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Medical Sciences Campus,Doctor Hassabi square

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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
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Saber Jafari Maskouni
Position
Student
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Bachelor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available