Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of black Raisin consumption on some cardiovascular risk factors, serum alonaldehyde and total antioxidant capacity in hyperlipidemic patients

Protocol summary

Summary

This study is a randomised controlled trial to determine the effect of Black Raisin on some cardiovascular risk factors, serum levels of Malondialdehyde (MDA) and total antioxidant capacity in 40 male and female patients with hyperlipidemia Referred to The Neshat clinic of Dezful county. The criteria for entering to this research are included : patients with Cholesterol above 200 milligrams per deciliter or Triglycerides above 150 mg per deciliter and The criteria for extracting to this research are included : Pregnant, liver disease, kidney disease, Hypothyroidism and Hyperthyroidism, Myocardial Infarction and Diabetes .Patients randomly are placed in two groups of intervention (n = 20) and ontrol (n = 20). Intervention group consumes 90 gram black Raisin daily for 5 weeks and the control group receives no intervention. Amount of energy and macronutrients received via Raisins are Replaced in intervention group. Anthropometric measurements, blood pressure, physical activity and 24-hour Dietary Recall are collected for three consecutive days at baseline and 5 weeks after the intervention . 10 cc blood will be taken after 12 to 14 hours of overnight fasting, at the beginning and after 5 weeks of Intervention. Biochemical analysis of Total Cholesterol, Triglycerides, LDL-C, HDL-C, LDL, will be done on fasting serum sampales ,as well as, serum levels of TAC and MDA will be evaluate. evaluating of Fibrinogen and factor VII on plasma samples will be done by related kits .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091624049N1**
Registration date: **2015-10-27, 1394/08/05**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-10-27, 1394/08/05

Registrant information

Name

Parvin Joola Joola

Name of organization / entity

Ahvaz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 4253 0416

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Recruitment status

Recruitment complete

Funding source

Ahvaz University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2015-09-29, 1394/07/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of black Raisin consumption on some cardiovascular risk factors, serum alonaldehyde and total antioxidant capacity in hyperlipidemic patients

Public title

Effect of black raisin consumption on some

cardiovascular risk factors

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Hypercholesterolemia patients who have high cholesterol of 200 mg dL or triglyceride levels over 200 milligrams per deciliter. Exclusion criteria: Hepatic or renal disorders, hypothyroidism and hyperthyroidism, myocardial infarction, diabetes, as well as samples that consume antioxidants, Pregnancy or hormone therapy in women

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Jundi Shapour Of Medical Sciences

Street address

Golestan Blvd.

City

Ahvaz

Postal code

6135715794

Approval date

2010-06-20, 1389/03/30

Ethics committee reference number

1394.103.IR.AJUMS.REC

Health conditions studied

1

Description of health condition studied

Hyperlepidemia

ICD-10 code

E78

ICD-10 code description

Disorders of lipoprotein metabolism and other lipidaemias

Primary outcomes

1

Description

Height

Timepoint

Baseline

Method of measurement

wall meter

2

Description

blood pressure

Timepoint

at baseline and 5 weeks after the intervention

Method of measurement

Aneroid sphygmomanometer dial, bulb, and air valve

3

Description

Weight

Timepoint

at basline and 5 weeks after the intervention

Method of measurement

Kilogram and with digital weight scale

4

Description

serum triglycerid

Timepoint

at basline and 5 weeks after the intervention

Method of measurement

Methods of enzymatic analysis

5

Description

Serum total cholesterol

Timepoint

at basline and 5 weeks after the intervention

Method of measurement

Methods of enzymatic analysis

6

Description

Serum levels of HDL

Timepoint

at basline and 5 weeks after the intervention

Method of measurement

Methods of enzymatic analysis

7

Description
Serum levels of LDL
Timepoint
at basline and 5 weeks after the intervention
Method of measurement
Friedewald formula

8

Description
Plasma levels of fibrinogen
Timepoint
at basline and 5 weeks after the intervention
Method of measurement
special kits and analyzer vicheles

9

Description
Plasma levels of coagulation factor VII
Timepoint
at basline and 5 weeks after the intervention
Method of measurement
Clotting time and spicial kit

10

Description
Serum levels of hs-CRP
Timepoint
at basline and 5 weeks after the intervention
Method of measurement
ELISA Kits

11

Description
TAC , serum total antioxidant capacity
Timepoint
at basline and 5 weeks after the intervention
Method of measurement
Colorimetric Test Kits

12

Description
MDA , Malondialdehyde
Timepoint
at basline and 5 weeks after the intervention
Method of measurement
TBARS

Secondary outcomes

empty

Intervention groups

1

Description
intervention group consume 90 grams black raisin daily for 5 weeks and Amount of energy and macronutrients that are received via raisins are Replaced in intervention group Dietary.
Category
Other

2

Description
The control group receives no intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Neshat clinic
Full name of responsible person
Dr Azam Sadeghinai
Street address
Enghelab ST. Neshat ST.
City
Dezful

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences, Vice Chancellor for Research and Technology
Full name of responsible person
Dr.Nader Saki
Street address
Golestan Blvd
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences, Vice Chancellor for Research and Technology
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
Ahvaz University of Medical Sciences
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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