

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Effects of yogurt and yogurt plus shallot consumption on lipid profiles in type 2 diabetic women

Protocol summary

Summary

The aim of this study is to determine the effect of yogurt and yogurt plus shallot intake on lipid profiles in type 2 diabetic women. This study will be a parallel randomized clinical trial. 48 women with type 2 diabetes will be enrolled to study. Inclusion criteria will be defined as female gender; age between 45-70 years old and not being on insulin therapy. Subjects will be excluded if pregnancy happens or participants use insulin therapy. Subjects will randomly be divided into two groups The first group will be received 150 milliliters of low fat yogurt (1.5% fat) daily and Second group will be received 150 milliliters of yogurt plus shallot (1.5% fat) daily. This study will be lasted for 10 weeks. Anthropometric indices will be measured before and after intervention period. Fasting blood sugar, Serum triglyceride, LDL-C, and total cholesterol concentration of each participant will be measured before and after 10 weeks intervention and the values will be compared within each group before and after intervention and between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508185062N10**

Registration date: **2016-02-27, 1394/12/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-27, 1394/12/08

Registrant information

Name

Reza Ghiasvand

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Food Security Research Center, Isfahan University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of yogurt and yogurt plus shallot consumption on lipid profiles in type 2 diabetic women

Public title

Effect of yogurt and yogurt plus shallot consumption on lipid profile

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: female gender; age between 45-70 years old and not use of insulin therapy Exclusion criteria: pregnancy; use of insulin therapy.

Age

From **45 years** old to **70 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 48

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.

City

Isfahan

Postal code

Approval date

2012-04-28, 1391/02/09

Ethics committee reference number

391098

Health conditions studied

1

Description of health condition studied

Type II diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

LDL-C

Timepoint

Before start of the intervention and after the intervention

Method of measurement

Blood biochemical test

2

Description

Total cholesterol

Timepoint

Before start of the intervention and after the intervention

Method of measurement

Blood biochemical test

3

Description

Triglyceride

Timepoint

Before start of the intervention and after the intervention

Method of measurement

Blood biochemical test

Secondary outcomes

1

Description

Fasting blood sugar

Timepoint

Before start of the intervention and after the intervention

Method of measurement

biochemical blood test

Intervention groups

1

Description

First intervention group: in the first group participants will be received 150 milliliter of low fat yogurt (1.5% fat) daily for 10 week

Category

Other

2

Description

Second intervention group: second group will be received 150 milliliter of low fat yogurt plus shallot (1.5% fat) daily for 10 week.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Endocrinology Research Center

Full name of responsible person

Sanaz Mehrabani, Master of nutrition Science

Street address

Sedigheh Tahere Research Center, Khorram St., Jomhori Eslami St.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Food Safety Research center

Full name of responsible person

Dr Leila Azadbakht

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Food Safety Research center

Proportion provided by this source**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***2****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Mehdi Nematbakhsh

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Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan

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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

Vice Chancellor for Research, Isfahan University of Medical Sciences

Proportion provided by this source**Public or private sector***empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Person responsible for general inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences, School of Nutrition and Food Science

Full name of responsible person

Sanaz Mehrabani

Position

Master of nutrition science

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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