

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1792 2742

###### Email address

ghiasvand@hlth.mui.ac.ir

###### 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.

##### City

Isfahan

## 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

**Street address**

Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan

**City**

Isfahan

**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****Type of organization providing the funding**

*empty*

## 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

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Full name of responsible person**

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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*