Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of dairy intake effects on the lipid profile, stress oxidative and inflammatory markers in diabetic patients

Protocol summary

Summary

To evaluate the effect of dairy intake on the lipid profile, stress oxidative and inflammatory markers in diabetic patients. A total of 90 patients with type 2 diabetes were randomly assigned to one of three treatment groups for 8 weeks. The groups received either no dairy product (n=30), 3 serving dairy product (n=30) or 5 serving dairy products (n=30). Serum lipid profile, stress oxidative and inflammatory markers were measured at baseline and at 8 weeks after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207261640N8**
Registration date: **2012-08-15, 1391/05/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-08-15, 1391/05/25

Registrant information

Name

Parvin Mirmiran

Name of organization / entity

Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Me

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2500

Email address

mirmiran@endocrine.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-09-01, 1391/06/11

Expected recruitment end date

2012-11-01, 1391/08/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of dairy intake effects on the lipid profile, stress oxidative and inflammatory markers in diabetic patients

Public title

Effect of dairy product on lipid profile, stress oxidative and inflammatory markers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age 18-60 y; no change in weight during 3 month previous; intake of dairy product 2 or less serving per day; no specific diet; body mass index 25-30 kg/m2; diabetic patients; intake of hypoglycemin drug. Exclusion criteria: using insulin infusion; liver and kidney disease; Allergy; intake of antioxidant and vitamin and mineral.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Siences
Street address
24 No., A'rabi St, Yemen St, velenjak, Chamran Exp.
City
Tehran
Postal code
Approval date
2012-07-25, 1391/05/04
Ethics committee reference number
451

Health conditions studied

1

Description of health condition studied
Diabetic patients
ICD-10 code
E12
ICD-10 code description
Malnutrition-related diabetes mellitus

Primary outcomes

1

Description
lipid profile
Timepoint
at beseline and 8 weeks after intervention
Method of measurement
biochemical analysis

2

Description
inflammatory marker
Timepoint
at baseline and 8 weeks after intervention
Method of measurement
biochemical analysis

3

Description
stress oxidative
Timepoint
at baseline and 8 weeks after intervention
Method of measurement
biochemival analysis

Secondary outcomes

1

Description
BMI
Timepoint
at baseline and 8 weeks after intervention
Method of measurement
scale

2

Description
blood pressure
Timepoint
at baseline and 8 weeks after intervention
Method of measurement
mercury sphgmomanometer

Intervention groups

1

Description
Control group receive no dairy products.
Category
N/A

2

Description
First intervention group receive 3 serving dairy products per day.
Category
Treatment - Other

3

Description
Second intervention group receive 5 serving dairy products per day.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran diabetes association
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Institute for Endocrine Sciences, Shahid Beheshti University of medical Sciences
Full name of responsible person
Fereidoun Azizi
Street address
24 No, A'rabi St, Yeman St, Velenjak, Chamran Exp
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Institute for Endocrine Sciences, Shahid Beheshti 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
Research Institute for Endocrine Sciences, Shahid Beheshti University od Medical Sciences
Full name of responsible person
Parvin Mirmiran
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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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