Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of camel milk on glycemic control and lipid profile of diabetic patients treated with long-acting insulin

Protocol summary

Summary

Objective: Evaluation of the effects of camel milk and cow milk on blood glucose, HbA1c, lipid profile, blood insuline and insuline dose in patients with diabetes treated with glargine. Design: Randomized Setting and conduct: A- Participants including major eligibility criteria - Major inclusion criteria: Patients with diabetes treated with glargine - Major exclusion criteria: having cardiovascular and renal diseases - Sample size: 40 B- Intervention: 500 cc camel milk or caw milk C- Intervention Time: 3 months D- Main outcome: Blood sugar, HbA1c, lipid profile, blood insuline and insuline dose

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310094794N10**
Registration date: **2016-03-02, 1394/12/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-03-02, 1394/12/12

Registrant information

Name

Fereidoun Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

azizi@endocrine.ac.ir

Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of camel milk on glycemic control and lipid profile of diabetic patients treated with long-acting insulin

Public title

camel milk and diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with diabetes treated with glargine; age range: 30 to 70 years old. Exclusion Criteria:pregnancy or lactation; smoking and alcohol consumption; Lactose intolerance; having cardiovascular disease, liver, lung, kidney and Chronic gastrointestinal and thyroid dysfunction; following from the weight loss diets two months prior to study; weight changes (increase or decrease) more than 5 kg two months prior to study

Age

From **30 years** old to **70 years** old

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

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Research Institute For Endocrine Sciences, Shahid Beheshti University of Medical S

Street address

Chamran Exp, Yemen street, Shahid Aerabi street, NO. 24

City

Tehran

Postal code

Approval date

2013-10-15, 1392/07/23

Ethics committee reference number

37ECRIES92/07/23

Health conditions studied

1

Description of health condition studied

Insulin-dependent diabetes

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Fasting blood glucose

Timepoint

Baseline and after 3 months

Method of measurement

Biochemical analysis

2

Description

HA1C

Timepoint

Baseline and after 3 months

Method of measurement

Biochemical analysis

3

Description

Lipid profile: total cholesterol, Triglyceride, HDL, LDL

Timepoint

Baseline and after 3 months

Method of measurement

Biochemical analysis

4

Description

Blood insuline

Timepoint

Baseline and after 3 months

Method of measurement

Biochemical analysis

5

Description

injectable insuline dose

Timepoint

Baseline and after 3 months

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Dietary Factors

Timepoint

Baseline and after 3 month

Method of measurement

24h dietary recall

2

Description

Body mass index

Timepoint

Baseline and after 3 months

Method of measurement

Anthropometric measurements

Intervention groups

1

Description

Intervention group: camel milk, 500 ml/day, 3 month

Category

Treatment - Other

2

Description
Control group: cow milk, 500 ml/day, 3 month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Clinic of Shohada Tajrish Hospital
Full name of responsible person
Dr Fereidoun Azizi
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical
Full name of responsible person
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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 Institute for Endocrine Sciences, Shahid Beheshti University of Medical
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
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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