

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial on the effect of kind of fermented milk on cardiometabolic risk factors, insulin resistance, some incretin hormones and related immunologic/inflammatory markers in 11-18-years-old adolescents with metabolic syndrome

Protocol summary

Summary

In this triple blind randomized clinical trial, after obtaining parent's informed consent and subject's assent, sixty 11-18 year-old eligible adolescents will be grouped into two arms using computerized block randomization (by sex and age group)(primary plan).The intervention will be 2 months consuming of fermented camel milk, 250(500) cc daily with major meals. the control subjects will receive fermented cow milk with similar taste and appearance. Outcome variables will be checked during the week before and the week after 2 months intervention. Three days food record and physical activity questionnaire will be used at baseline.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508081202N2**

Registration date: **2015-09-19, 1394/06/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-19, 1394/06/28

Registrant information

Name

Zahra Fallah

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 3321

Email address

z_fallah@mail.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellory for research and technology Isfahan University of Medical sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2015-11-22, 1394/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial on the effect of kind of fermented milk on cardiometabolic risk factors, insulin resistance, some incretin hormones and related immunologic/inflammatory markers in 11-18-years-old adolescents with metabolic syndrome

Public title

Effect of a kind of fermented milk on metabolic syndrome in adolescents

Purpose

Prevention

Inclusion/Exclusion criteria

Major inclusion criteria: 11-18 years old; both genders; Iranian nationality; diagnosed with Metabolic syndrome. Major exclusion criteria: other diseases; not consuming milk product for more than 3 consecutive or 7 intermittent days; side effects like allergic reactions.

Age

From **11 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

If the patient recruitment lasts too long, the parallel assignment will be changed to crossover. If good compliance is guaranteed, the amount of fermented milk will be raised to 500 cc daily.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan regional ethics committee

Street address

Isfahan University of Medical Sciences, Hezarjerib Avenue

City

Isfahan

Postal code

Approval date

2014-09-29, 1393/07/07

Ethics committee reference number

193059

Health conditions studied

1

Description of health condition studied

Metabolic Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Selected cardiometabolic risk factors

Timepoint

During the week before and the week after 2 months intervention

Method of measurement

Blood biochemistry and physical examinations

Secondary outcomes

1

Description

Insulin resistance level

Timepoint

During the week before and the week after 2 months intervention

Method of measurement

Blood test and calculation

2

Description

Incretine hormones level

Timepoint

During the week before and the week after 2 months intervention

Method of measurement

Blood test

3

Description

Some immuno/inflammatory biomarkers

Timepoint

During the week before and the week after 2 months intervention

Method of measurement

Blood test

Intervention groups

1

Description

Intervention: 250 cc fermented camel milk daily for 2 months

Category

Treatment - Other

2

Description

Control:250-500 cc fermented cow milk daily for two months

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin Hospital

Full name of responsible person

Dr. Zahra Fallah

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mehdi Nematbakhsh

Street address

Vice chancellory for Research-Building No 4, Isfahan university of Medical Sciences, Hezarjerib Avenue

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Zahra Fallah

Position

GP / PhD student

Other areas of specialty/work

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Other areas of specialty/work

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Fax

Email

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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