

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Investigating the effect of probiotic and 25OHD3 with low-calorie diet on satiety and hunger hormones and vitamin D in obese people

Protocol summary

Study aim

Comparison the effect of taking yogurt enriched with probiotic and 25OHD3 and low calorie diet on satiety and hunger hormones and 25OHD3 in obese people

Design

A randomised, double blinded, controlled clinical trial with four parallel group design

Settings and conduct

This study will be conducted at health faculty. volunteers randomly will be allocated to one of the 4 groups by using 4 randomized blocks. Individuals will complete physical activity questionnaire (comparing physical activity pattern between 4 groups in the end of intervention), consent form and demographic information. Height will determined with a stadiometer to the nearest of 0.1 cm. Weight and body composition will measured by using body analyzer. After 12-14 h of fasting, venous blood samples will collected. In this study, factory will choose 4 different codes for 4 kind of yogurts instead of their names, therefore main researcher, participant and yogurt distributor will be blind from start to the end of study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to lose weight, Age between 18 and 60, BMI between 29 and 51, Filling the consent form, Absence of associated co-morbidities, Absence of breast-feeding, pregnancy or menopause, No history of hormone disorders, No intake of vitamin D for 1 months before the intervention. Non inclusion criteria includes: have allergy to yogurt, Using weight loss regimens

Intervention groups

The intervention groups including 3 group receiving probiotic yogurt and low calorie diet; probiotic yogurt enriched with 25OHD3 and low calorie diet; yogurt enriched with 25OHD3 and low calorie diet; traditional yogurt and low calorie diet

Main outcome variables

Changes in ghrelin, peptid YY, glucagon like peptid,

25OHD3 and anthropomorphic factors

General information

Reason for update

for filling out the date of finishing recruiting and clinical trial and

Acronym

IRCT registration information

IRCT registration number: **IRCT20120525009856N7**

Registration date: **2018-06-13, 1397/03/23**

Registration timing: **prospective**

Last update: **2019-12-30, 1398/10/09**

Update count: **1**

Registration date

2018-06-13, 1397/03/23

Registrant information

Name

Yahya Pasdar

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1828 1991

Email address

yahya.pasdar@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-05-20, 1397/02/30

Actual recruitment start date

2018-11-13, 1397/08/22

Actual recruitment end date

2018-12-10, 1397/09/19

Trial completion date

2019-04-06, 1398/01/17

Scientific title

Investigating the effect of probiotic and 25OHD3 with low-calorie diet on satiety and hunger hormones and vitamin D in obese people

Public title

Investigating the synergist effect of probiotic and vitamin D in obesity

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to lose weight Age between 18 and 60 Body mass index (BMI) between 29 and 51 Filling the consent form of the present project Absence of associated co-morbidities (insulin dependent diabetes, chronic kidney disease, cancer and anemia) Absence of breast-feeding, pregnancy or menopause No history of hormone disorders including: hypothyroid, hyperthyroid, polycystic ovary syndrome (PCOS), breast and ovary cyst No intake of vitamin D for 1 months before the study initiation No antibiotic treatment for the last 1 month No intake of probiotic, prebiotic and synbiotic supplement and/ or probiotic, prebiotic and synbiotic enriched products 1 month before the study initiation

Exclusion criteria:

Individuals who had allergy to yogurt Individuals who use certain regimens or weight loss regimens Individuals who use any kind of vitamin supplements Individuals who use any kind of weight loss drug or supplement women who use contraceptive drugs

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **140**

Actual sample size reached: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual randomization with out layering, Four blocks randomized Blocks will determined daily and write on paper Selecting randomized blocks will done by somebody except researcher.

Blinding (investigator's opinion)

Double blinded

Blinding description

The appearance of yogurts are the same The main investigator will not be aware of yogurt's content and the

group which subjects are in. The person who analyze date will be unaware of the group which each subject belong.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Kermanshah University of Medical Sciences Ethics Committee

Street address

Deputy of Research and Technology, Building No. 2 of Kermanshah University of Medical Sciences, Naft Square, Shahid Beheshti blvd

City

Kermanshah

Province

Kermanshah

Postal code

6719851351

Approval date

2018-02-28, 1396/12/09

Ethics committee reference number

IR.KUMS.REC.1396.651

Health conditions studied**1****Description of health condition studied**

Obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

Primary outcomes**1****Description**

25(OH)D3

Timepoint

In base line (before intervention) and 10 months after the beginning of intervention

Method of measurement

By using ELISA Kit

2**Description**

Ghrelin hormone
Timepoint
In base line (before intervention) and 10 months after the beginning of intervention
Method of measurement
By using ELISA Kit

3

Description
Peptid YY hormone
Timepoint
In base line (before intervention) and 10 months after the beginning of intervention
Method of measurement
By using ELISA Kit

4

Description
GLP-1 hormone
Timepoint
In base line (before intervention) and 10 months after the beginning of intervention
Method of measurement
By using ELISA Kit

5

Description
Waist Circumference
Timepoint
In base line (before intervention) and 10 months after the beginning of intervention
Method of measurement
In term of centimeter by Tape measure

6

Description
Body Fat Mass
Timepoint
In base line (before intervention) and 10 months after the beginning of intervention
Method of measurement
in term of kg, by using body analyzer instrument

7

Description
Hip Circumference
Timepoint
In base line (before intervention) and 10 months after the beginning of intervention
Method of measurement
In term of centimeter by Tape measure

Secondary outcomes

1

Description
Serum LDL

Timepoint
before and after 10 weeks
Method of measurement
by using Friedewald equation

2

Description
Serum HDL
Timepoint
before and after 10 weeks
Method of measurement
by using biochemical kits (mono bind ELISA kit)

3

Description
serum fasting blood sugar
Timepoint
before and after 10 weeks
Method of measurement
by using biochemical kits (mono bind ELISA kit)

4

Description
serum total cholestrol
Timepoint
before and after 10 weeks
Method of measurement
by using biochemical kits (mono bind ELISA kit)

5

Description
serum Total triglycerides
Timepoint
before and after 10 weeks
Method of measurement
by using biochemical kits (Monobind ELISA kit)

Intervention groups

1

Description
The first intervention group: low calorie diet and 100 g/day yogurt enriched with 1000 IU 25OHD3
Category
Lifestyle

2

Description
The second intervention group: low calorie diet and 100 g/day probiotic yogurt enriched with 1000 IU 25OHD3
Category
Lifestyle

3

Description
The third intervention group: low calorie diet and 100

g/day probiotic yogurt

Category

Lifestyle

4

Description

The control group: low calorie diet and 100 g/day traditional yogurt.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Behbud Nutrition and Diet Therapy Clinic

Full name of responsible person

Dr yahya pasdar

Street address

No 1, Behbud Nutrition and Diet Therapy Clinic, First of Movayed Av, Ejlaleye Bridge, Shahr-dari Parking, kermanshah, Kermanshah

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6713743413

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yahya.pasdar@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

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Grant name

خالي

Grant code / Reference number

خالي

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

No

Title of funding source

Medical univercity of kermanshah

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Shima Hajipour

Position

MS.c student in Nutrition Sciences/ chief cooperater of plan

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

Public Health faculty, Next to the Farabi Hospital, Dolat Ababd blvd, Isar Square, Imam Hosein Exp

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Yahya Pasdar

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

Name of organization / entity
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Shima Hajipour
Position
MS.c student in Nutrition Sciences/ chief cooperator of plan
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Bachelor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available