Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 recieving 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 cholostrol

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, Shahrdari Parking, kermanshah, Kermanshah

City

Kermanshah

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Postal code

6713743413

Phone

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Email

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

Street address

Vice– Chancellery of Research & Technology Affairs, Building No. 2 of Kermanshah University of Medical Sciences, Naft Square, Shahid Beheshti blvd,

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fnajafi@kums.ac.ir

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 cooperator 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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Phone

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Email

shima.hajipour.1t@gmail.com

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

Street address

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Dolat Ababd blvd, Isar Square, Imam Hosein Exp

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Person responsible for updating data

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 cooperator of plan

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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