Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of synbiotic supplementation on anthropometric indices, Inflammatory and hormone profiles in patients with hypothyroidism

Protocol summary

Study aim
Determination of the effects of synbiotic supplementation on anthropometric indices, Inflammatory and hormone profiles in hypothyroid patients

Design
This is a randomized, placebo-controlled, double-blind parallel-group clinical trial. Fifty six participants will randomly allocated to receive synbiotic per day (n = 28) or placebo (n = 28).

Settings and conduct
In this study, people with hypothyroidism who are being treated with standard dose levothyroxine will recruited from Isfahan Endocrine & Metabolism Research Center (IEMRC) and Al-Zahra clinic , Isfahan, Iran. Subjects will stratified according to gender. Random assignment will done by the use of table of random numbers. The enrolling participants, and assigning participants to the groups will carried out by a trained nutritionist.The synbiotic supplement and its placebos will be packed in similar boxes, and the researcher and the patients will not be aware of the content of the pack until the end of the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria:1) Age of 18 to 65 years; 2) Hypothyroid patients with a history of treatment for more than one year using levothyroxine sodium; 3) TSH is at least one year with a constant dose of levothyroxine in the normal range; 4) No smoking and alcohol; 5) Non pregnant, non-lactating; 6) Willingness to participation in the study Exclusion criteria: 1) Thyroid cancer; 2) Intestinal malabsorption (history of obstructive surgery, inflammatory bowel disease, celiac disease); 3) Antibiotic use; 4) Acute and chronic infectious diseases

Intervention groups
Individuals will randomly divided into two groups to receive 500 mg familact synbiotic supplementation or placebo per day for 8 weeks.

Main outcome variables
Weight;Waist circumference;BMI;WHR;Systolic blood pressure;Diastolic blood pressure;C-reactive protein;Thyroid-stimulating hormone;FreeT3;Anti-thyroid peroxidase

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121216011763N35**
Registration date: **2018-10-28, 1397/08/06**
Registration timing: **prospective**

Last update: **2018-10-28, 1397/08/06**
Update count: **0**

Registration date
2018-10-28, 1397/08/06

Registrant information

Name
Gholamreza Askari

Name of organization / entity
Isfahan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-06, 1397/08/15

Expected recruitment end date
2019-03-01, 1397/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of synbiotic supplementation on anthropometric indices, Inflammatory and hormone profiles in patients with hypothyroidism

Public title

synbiotic and hypothyroidism

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 65 years Hypothyroid patients with a history of treatment for more than one year using levothyroxine (sodium) TSH is at least one year with a constant dose of levothyroxine in the normal range No smoking and alcohol Non pregnant, non-lactating Non-use of drugs that affect metabolism and absorption of levothyroxine include: iron sulfate, magnesium sulfate, warfarin, luvastatin, amiodarone, sumatropin, calcium carbonate, orlistat, multivitamin and minerals, theophylline, ritunavir, rifampin, phenytoin, karmazapine, Phenobarbital, Sucralfate, Aluminum hydroxide, Sertraline, Bile doses, Estrogens and other estrogen modifying drugs, Proton pump suppressants, Phosphate binders People who, after explaining the work, were willing to cooperate and answer questions and conduct experiments

Exclusion criteria:

Thyroid cancer Intestinal malabsorption (history of obstructive surgery, inflammatory bowel disease, celiac disease) Antibiotic use Acute and chronic infectious diseases Use of drugs that affect the absorption and metabolism of levothyroxine, including (iron sulfate, magnesium sulfate, warfarin, luvastatin, amiodarone, sumatropin, calcium carbonate, orlistat, multivitaminomineral, theophylline, ritunavir, rifampin, Tween, Karmazpine, Phenobarbital, Sucralfate, Aluminum Hydroxide, Sertraline, Bile Drug, Estrogen and other estrogen modifying drugs, proton pump inhibitor drugs, phosphate binders)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly, based on the permuted block randomization method, using blocks of 4 that will be blocked based on gender variables and will be assigned to one of two synbiotic and placebo groups.The enrolling participants, and assigning participants to the groups will carried out by a trained nutritionist. Researchers will not informed about randomization process until completion of data analyses.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind clinical trial (participant, researcher). The familact synbiotic supplement and its placebo will be produce by Zist takhmir company . Synbiotic supplement and its placebos will in the same form of package and the patients and researcher will not aware of the content of the pack until the end of trial.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjarib Ave., Isfahan University of Medical Sciences

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2018-10-19, 1397/07/27

Ethics committee reference number

IR.MUI.MED.REC.1397.102

Health conditions studied

1

Description of health condition studied

Hypothyroidism

ICD-10 code

E03.9

ICD-10 code description

Hypothyroidism, unspecified

Primary outcomes

1

Description
Thyroid-stimulating hormone
Timepoint
Before the start of the study and 8 weeks after the intervention
Method of measurement
enzyme-linked immunosorbent assay (ELISA)

2

Description
Free triiodothyronine (FT3)
Timepoint
Before the start of the study and 8 weeks after the intervention
Method of measurement
enzyme-linked immunosorbent assay (ELISA)

Secondary outcomes

1

Description
Anti-thyroid peroxidase
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
enzyme-linked immunosorbent assay (ELISA)

2

Description
C-reactive protein
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Laboratory analysis

3

Description
Weight
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Digital scale

4

Description
Waist Circumference
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
non-stretching tape measure

5

Description
Waist / hip ratio - WHR
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
non-stretching tape measure

6

Description
Systolic blood pressure
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Sphygmomonometer

7

Description
Diastolic blood pressure
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Sphygmomonometer

8

Description
Body Mass Index
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Dividing the weight into kilograms by squared height by meter

9

Description
Depression score
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Depression Anxiety and Stress Scales (DASS-21)

10

Description
Anxiety score
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Depression Anxiety and Stress Scales (DASS-21)

11

Description
Stress score
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Depression Anxiety and Stress Scales (DASS-21)

12

Description
Appetite
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Visual Analogue Scale

13

Description
Multidimensional Fatigue Inventory
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
multidimensional fatigue inventory (MFI-20)

14

Description
Fatigue Intensity
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Fatigue severity scale (FSS)

15

Description
Quality of Life
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
World Health Organization Quality of Life Questionnaire 26 questions (WHOQOL-BREF)

16

Description
Constipation , bowel habits, abdominal symptoms
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Constipation , bowel habits, abdominal symptoms questionnaire

17

Description
Body fat percentage
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Bioimpedance

Intervention groups

1

Description
Intervention group: A daily dose of 500 mg of FimiLact synbiotic capsule was read 2 hours after Levothyroxine tablet for 8 weeks (dosage of 1 capsule per day). Synthetic FamiLact Synthetic Foam Supplement will be manufactured by Iranian Zist Takhmir Company.
Category
Treatment - Other

2

Description
Control group: Each day, 1 placebo (starch 375 mg, lactose 22 mg, magnesium stearate 1 mg, 1 mg silicon dioxide, 1 mg talc) will receive 2 hours after levothyroxine for 8 weeks.The placebo will be made by Tehran Zist Takhmir Company.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrine & Metabolism Research Center
Full name of responsible person
Gholamreza Askari
Street address
Korram Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
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Hezar Jarib Ave, Isfahan University of Medical Sciences
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sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

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

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Full name of responsible person

Dr Gholamreza Askari

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr Gholamreza Askari

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The collected deidentified for the primary outcome measure only will be shared.

When the data will become available and for how

long

starting 12 months after publication.

To whom data/document is available

Available for people working in academic institutions

Under which criteria data/document could be used

The data will provide for educational use.

From where data/document is obtainable

Dr. Gholamreza Askari askari@mui.ac.ir

What processes are involved for a request to access data/document

The data will send as soon as possible, after receiving the request.

Comments