Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Synbiotic supplementation on gut microbiome metabolite, inflammatory and cardiovascular factors in mild subclinical hypothyroid patients: A double-blind placebo-controlled randomized clinical trial

Protocol summary

Study aim

Determining the effect of synbiotic supplementation on gut microbiome metabolites and some inflammatory and cardiovascular factors in mild subclinical hypothyroid patients

Design

A randomized double-blind controlled,clinical trial with parallel-group, on 48 patients.

Settings and conduct

The study will be conducted at Sina hospital of Tabriz University of Medical Sciences and the supplementation duration will be 8 weeks. The Synbiotic and placebo packages will be coded by the person responsible for preparing them, and the main investigators and the patients will be blinded to the type of supplement each group receives.

Participants/Inclusion and exclusion criteria

Inclusion criteria: newly diagnosed patients with subclinical hypothyroidism, TSH level between 4 and 10 IU/ml, age between 20-65 years, willingness to cooperate in the project, suffering from mild subclinical hypothyroidism. Exclusion criteria: hormone therapy and use of hormonal drugs, contraceptive drugs, anti-inflammatory drugs, blood lipid-lowering drugs, use of any probiotic supplements in the last 3 months before the study and during the study, use of Antibiotics during the study

Intervention groups

The intervention group received 1 synbiotic capsule daily with a microbial load of 109 CFU after lunch, and the placebo group also received 1 placebo capsule daily, which includes cellulose, non-absorbable silicon dioxide, prepared in the Faculty of Pharmacy after lunch for 2 months (60 day).

Main outcome variables

Intestinal microbiome metabolite (LPS), cardiovascular indices (TC, LDL, apoA1, Apo B), IL-6 and TNF-α

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121224011867N2**
Registration date: **2024-05-28, 1403/03/08**
Registration timing: **prospective**

Last update: **2024-05-28, 1403/03/08**
Update count: **0**

Registration date

2024-05-28, 1403/03/08

Registrant information

Name

Naimeh Mesri Alamdari

Name of organization / entity

Faculty of Health and Nutrition, Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

mesri65@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-22, 1403/06/01

Expected recruitment end date

2024-11-20, 1403/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Synbiotic supplementation on gut microbiome metabolite, inflammatory and cardiovascular factors in mild subclinical hypothyroid patients: A double-blind placebo-controlled randomized clinical trial

Public title
Investigating the effect of synbiotics in mild subclinical hypothyroid patients

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Newly diagnosed patients with mild subclinical hypothyroidism TSH level between 4 and 10 IU/ml Willingness to cooperate in the project 20-65 years Suffering from mild subclinical hypothyroidism

Exclusion criteria:
Hormone therapy and the use of hormonal drugs The contraceptive drugs usage The anti-inflammatory drugs usage The blood lipid-lowering drugs consumption The probiotic supplements consumption in the last 3 months before the study and during the study The antibiotic drugs usage during the study Sẏnbiotic supplement intolerance during the study Immune system disorders Immunosuppressive drugs or chemotherapy consumption Cardiovascular diseases, active ulcerative colitis, short bowel syndrome, acute and chronic infectious diseases History of drug or food allergies Pregnancy and breastfeeding Smoking Alcohol consumption

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Subjects are randomly assigned 1:1 into 2 intervention and placebo groups. Allocation to study groups is done based on permuted block randomization using RAS software and on random blocks that will be matched in age and sex.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study's main investigator and patients will be blind (synbiotic or placebo). The person is responsible for preparing the supplement (who is completely unrelated to the study) will be asked to assign a three-digit code to each of the two supplements (synbiotic and placebo) and keep the codes for himself until the end of the study and data analyses.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of Tabriz University of Medical Sciences

Street address
Third Floor, Central Building (2), Tabriz University of Medical Sciences, Golghasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
00984133344280

Approval date
2024-04-22, 1403/02/03

Ethics committee reference number
IR.TBZMED.REC.1403.052

2

Ethics committee

Name of ethics committee
Research Ethics Committees of Tabriz University of Medical Sciences

Street address
Third Floor, Central Building (2), Tabriz University of Medical Sciences, Golghasht Street

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Postal code
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Approval date
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Ethics committee reference number
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Health conditions studied

1

Description of health condition studied
Mild subclinical hypothyroidism

ICD-10 code
E02

ICD-10 code description
Subclinical iodine-deficiency hypothyroidism

Primary outcomes

1

Description
Gut microbiome metabolite (LPS)
Timepoint
Before the intervention and two months after the intervention
Method of measurement
By laboratory ELISA kits

Secondary outcomes

1

Description
Total cholesterol (TC)
Timepoint
Before the intervention and two months after the intervention
Method of measurement
By laboratory ELISA kits

2

Description
Triglyceride (TG)
Timepoint
Before the intervention and two months after the intervention
Method of measurement
By laboratory ELISA kits

3

Description
Apo A1
Timepoint
Before the intervention and two months after the intervention
Method of measurement
By laboratory ELISA kits

4

Description
Apo B
Timepoint
Before the intervention and two months after the intervention
Method of measurement
By laboratory ELISA kits

Intervention groups

1

Description
Intervention group: synbiotic capsule which contains bacterial species Lactobacillus rhamnoses, Lactobacillus plantarum, Lactobacillus casei, Lactobacillus helveticus, Lactobacillus acidophilus, Lactobacillus bulgaricus, Lactobacillus gasseri, Bifidobacterium bifidum, Bifidobacterium lactis, Bifidobacterium breve. , Bifidobacterium longum, Streptococcus thermophile and prebiotic fructooligosaccharide with a microbial load of 109 CFU after lunch once a day.
Category
Prevention

2

Description
Control group: The placebo group will receive 1 placebo capsule per day, which includes cellulose compounds, non-absorbable silicon dioxide prepared in the Faculty of Pharmacy, after lunch for 2 months (60 days).
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers of Tabriz University of Medical Sciences
Full name of responsible person
Naimeh Mesri Alamdari
Street address
Endocrine Research Center, Nutrition faculty, Attar Neyshabouri Street, Golgasht Avenue, CityTabriz
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West Azarbaijan
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5166614711
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research vice- chancellor of Tabriz university of medical sciences
Full name of responsible person
Parviz Shahabi
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East Azarbaijan

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5166616471
Phone
+98 41 3335 7311
Email
parvizshahabi@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Research vice- chancellor of Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Naimeh Mesri Alamdari
Position
academic board
Latest degree
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Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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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
Yes - There is 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

Data collected for the primary outcomes will be shared.

When the data will become available and for how long

access starting 12 months after publication

To whom data/document is available

The data will only be available for people working in academic institutions.

Under which criteria data/document could be used

The data of the present study will only be accessible by other researchers, for conducting Meta-analysis.

From where data/document is obtainable

To receive the data, contact the project manager (Naimeh Masri Alamdari). Postal address: Tabriz University of Medical Sciences - Endocrine Research Center Email: mesri65@gmail.com Academic email: n.mesri@tbzmed.ac.ir

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

mesri65@gmail.com n.mesri@tbzmed.ac.ir

Comments