Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of probiotics on thyroid function and fatigue score in patients with hypothyroidism

Protocol summary

Study aim
The effect of probiotics on thyroid tests and FATIGUE SCORE in patients with hypothyroidism
Design
Clinical trial with control group, with parallel groups, double-blind, randomized, on 80 patients
Settings and conduct
Initially, physical examination including height, weight, and BMI is performed on patients. Then, to measure the tests, including TSH, FreeT4, FreeT3, TG, CHOLESTEROL, LDL, HDL, LP (a), they are referred to the hospital laboratory. Then, patients are completely randomly divided into intervention and control groups. In the intervention group, treatment with probiotic pills is given in the amount of 500 mg capsules daily and in the control group, a placebo is prescribed. After 12 weeks, the effect of the above treatments on the initial laboratory indicators as well as on weight, blood pressure, BMI, and FATIGUE SCORE will be evaluated and compared in two groups.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with hypothyroidism, aged between 18 and 65 years, with at least 3 months of medication. patients that have taken a fixed dose of levothyroxine and are still euthyroid during this time. Exclusion criteria: History of thyroidectomy due to thyroid cancer,Have a history of taking antibiotics in the last three months,Have a history of alcohol and smoking,Be pregnant or breastfeeding,History of taking or taking levothyroxine-lowering drugs,Have levothyroxine dose changes during the study,Patient dissatisfaction to continue cooperation
Intervention groups
Daily intake of one probiotic tablet in excess of CFU 109 equivalent to 500 mg capsules for 12 weeks
Main outcome variables
Laboratory indicators AST, ALT, ALP, BILL T, D, TG, Cholesterol, LDL, HDL, TSH, freeT4, freeT3, and The fatigue score questionnaire are checked at the beginning of the study and after 12 weeks.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210829052320N1**
Registration date: **2022-02-24, 1400/12/05**
Registration timing: **prospective**

Last update: **2022-02-24, 1400/12/05**
Update count: **0**
Registration date
2022-02-24, 1400/12/05

Registrant information
Name
Ali Mofatteh
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-04-21, 1401/02/01
Expected recruitment end date
2023-04-21, 1402/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Effect of probiotics on thyroid function and fatigue score in patients with hypothyroidism

Public title
Effect of probiotics onthyroid function and fatigue score in patients with hypothyroidism

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Hypothyroid or subclinical hypothyroid patient with treatment indication At least 3 month on levothyroxine Euthyroid during this 3month

Exclusion criteria:
Recent thyroidectomy Using Antibiotics in last 3 month Being Alcohol user or smoker Being peregnant or breastfeeding Using drugs lowering levothyroxine consumption Changing levothyroxine doses during follow up time

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block randomization will be used as a reliable randomization method that leads to a balanced allocation of individuals in treatment groups at the end of each block. For this purpose, an online website addressed as (https://www.sealedenvelope.com/simple-randomiser/v1/lists) is used to create random blocks with different sizes depending on the total sample and proposed block sizes (4 and 6). Each block content is sealed. One of the block is randomly chosen when a patient refers. The patient is assigned to one of the study arms depending on the block content. Similarly, after the completion of the first block, the second block is randomly selected and this continues until the last block and the last patient is assigned to the study arms. By assigning the last sheet of the last block, the patients are grouped equally in the two study arms.

Blinding (investigator's opinion)
Double blinded

Blinding description
After entering the study, patients choose a card from the secretary. They will receive placebo for even numbers and intervention medication for odd numbers. The secretary will enter the code in the form of each patient's form so the researcher and the participant will not be aware of the meaning of the code. Codes will be reserved until the end of the study and data analysis. The drug and placebo will be placed in the same boxes so the patients can not understand which are drug or placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Faculty of Medicine, east door of Ferdowsi University campus, Azadi Square

City
mashhad

Province
Razavi Khorasan

Postal code
9177948564

Approval date
2021-05-11, 1400/02/21

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.188

Health conditions studied

1

Description of health condition studied
Hypothyroidism

ICD-10 code
E03.8

ICD-10 code description
Central hypothyroidism

Primary outcomes

1

Description
Serum TSH levels

Timepoint
Before the intervention and after 12 weeks of medication

Method of measurement
blood test

2

Description
Serum free T4 levels
Timepoint
Before the intervention and after 12 weeks of medication
Method of measurement
Blood test

3

Description
Serum free T3 levels
Timepoint
Before the intervention and after 12 weeks of medication
Method of measurement
Blood test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Lactocar 500 mg probiotic capsules once a day for 12 weeks
Category
Treatment - Drugs

2

Description
Control group: 500mg placebo capsules for 12 weeks, 1 capsule daily
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Mina Akbari Arad
Street address
Ghaem Hospital, Ahmadabad St., Mashhad, Khorasan Razavi
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Quaem.Medical.Center@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Vice chancellor for research and technology, Mashhad University of Medical Sciences, Daneshgah Avenue
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vcresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mina Akbari Rad
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
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Person responsible for scientific inquiries

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Position
associate professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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