

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of Synbiotics versus Placebo in Subclinical hypothyroid patients

Protocol summary

Study aim

comparing the levels of TSH, FT4, and FT3 in subclinical hypothyroid patients after treated with synbiotics versus placebo

Design

The present study is a randomized double-blind clinical trial study that will be conducted on 40 patients. Random allocation based on the table of random numbers, the synbiotic replacement blocks and its placebo will be divided into similar boxes.

Settings and conduct

In the present study, which will be conducted at Ali Bin Abi Taleb Hospital in Zahedan, 40 patients with subclinical hypothyroidism will be included in the study. treatment will generally be done within 8 weeks. The drug packages are completely similar in terms of shape and the patient and the plan administrator will not be aware of the contents of the packages. Fasting blood samples will be taken from these people before and after receiving the supplement or placebo to measure the level of thyroid hormones.

Participants/Inclusion and exclusion criteria

The inclusion criteria for this study are: age between 18 and 70 years The Exclusion criteria are: lack of consent of the patients to enter the study, suffering from thyroid nodule, cancer, any type of infection or inflammatory disease, coronary artery disease, heart failure, gastrointestinal diseases, pregnancy, smoking addiction. and alcohol and antibiotic use in the last 3 months.

Intervention groups

After 8 weeks from the start of treatment (taking one synbiotic or placebo pill per day), TSH, FT4, anti tpo and FT3 tests are evaluated in both intervention and control groups.

Main outcome variables

TSH, FT4, FT3 and Anti Tpo; Time to evaluate thyroid tests in patients; Subclinical hypothyroid patients treated with probiotics and patients treated with placebo

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221124056594N1**

Registration date: **2023-02-06, 1401/11/17**

Registration timing: **prospective**

Last update: **2023-02-06, 1401/11/17**

Update count: **0**

Registration date

2023-02-06, 1401/11/17

Registrant information

Name

Maryam Pourmorteza

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 54 3348 2233

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-19, 1401/11/30

Expected recruitment end date

2023-07-05, 1402/04/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Synbiotics versus Placebo in Subclinical hypothyroid patients		entering the patient in the study to the completion of the study, data collection and information analysis, the contents of the two drug groups are not known.	
Public title	effect of Synbiotics in Subclinical hypothyroid patients	Placebo	Used
Purpose	Treatment	Assignment	Parallel
Inclusion/Exclusion criteria	Other design features		
Inclusion criteria:	Secondary Ids		
Confirmation of clinical hypothyroidism based on laboratory tests of TSH, T3, T4 and Anti-TPO and confirmation of an endocrinologist Lack of indication for treatment with levothyroxine	empty		
Exclusion criteria:	Ethics committees		
Having a thyroid nodule cancer Having any type of infection or inflammatory disease Absence of gastrointestinal diseases pregnancy Addiction to smoking, alcohol Use of antibiotics in the last 3 months	1		
Age	Ethics committee		
From 18 years old to 70 years old	Name of ethics committee		
Gender	Ethics committee of Zahedan University of Medical Sciences		
Both	Street address		
Phase	Dr. Hasabi square		
3	City		
Groups that have been masked	Zahedan		
• Participant • Care provider • Investigator • Data analyser	Province		
	Sistan-va-Balouchestan		
	Postal code		
	9816743463		
	Approval date		
Sample size	2022-10-24, 1401/08/02		
Target sample size: 40	Ethics committee reference number		
More than 1 sample in each individual	IR.ZAUMS.REC.1401.300		
Number of samples in each individual: 2	Health conditions studied		
Fasting blood sample to measure thyroid hormone levels	1		
Randomization (investigator's opinion)	Description of health condition studied		
Randomized	Subclinical iodine-deficiency hypothyroidism		
Randomization description	ICD-10 code		
Random assignment of patients to two groups is done by permuted block stratified randomization method. In this way, first, eligible referring patients are classified according to age and gender in the order of entry. Then they are assigned to the desired group based on blocks of 4 (consisting of two groups A and B and two repetitions for each) randomly selected from among all the possible states of permutations. These blocks were created using statistical software R version 4.0.2.	E02		
Blinding (investigator's opinion)	ICD-10 code description		
Double blinded	Subclinical iodine-deficiency hypothyroidism		
Blinding description	Primary outcomes		
Double blinding method is used in this research. So that the researcher and the subjects will not be aware of the intended intervention. Patients will be treated by the drug packages predetermined by the project supervisor. The drug packages are completely similar in terms of shape and the patient and plan executive will not be aware of the contents of the packages. In the data analysis stage, the analysis will be done by the project advisor and the project manager, who are not aware of the contents of the drug packages, and only the patient group (group 1 or 2) will be determined for data analysis. Therefore, according to this working method, from the stage of	1		
	Description		
	Thyroid Hormones		
	Timepoint		
	At the beginning of the study (before the start of the intervention) and eight weeks after the start of synbiotic		
	Method of measurement		
	Fasting blood sample to measure the level of thyroid hormones by chemiluminescence method		
	Secondary outcomes		
	empty		

Intervention groups

1

Description

Intervention group: All people diagnosed with subclinical hypothyroidism are randomly divided into two intervention and control (placebo) groups. After 8 weeks from the start of treatment, both groups are evaluated. As a probiotic, the drug familact from the brand of Danesh Banian bio-fermentation company, made in Iran, is used. The synbiotic capsule will contain the following 7 freeze-dried probiotic strains. Lactobacillus casei, 2 x 10⁹ CFU Lactobacillus acidophilus, 1.5 x 10⁹ CFU Lactobacillus Rhamnosus, 2 x 10⁸ CFU Lactobacillus bulgaricus, 2 x 10¹⁰ CFU Bifidobacterium Breve, 7 x 10⁹ CFU BIFIDOBACTOCTOMICS

Category

Treatment - Drugs

2

Description

Control group: Placebo will be prepared from Danesh Bonyan bio-fermentation company, made in Iran. Placebo contains: 375 mg of starch, 22 mg of lactose, 1 mg of magnesium stearate, 1 mg of silicon dioxide and 1 mg of talc.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Aliebne Abitaleb hospital

Full name of responsible person

Maryam Pourmorteza

Street address

Highway KHaliJe Fars, Aliebne Abitaleb hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Nourmohammad Bakhshani

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Maryam Pourmorteza

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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