

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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)

##### Phone

+98 54 3348 2233

##### Email address

shnosratzehi123@gmail.com

##### 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

**Public title**

effect of Synbiotics in Subclinical hypothyroid patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

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

**Exclusion criteria:**

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

**Age**

From **18 years** old to **70 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Data analyser

**Sample size**

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

Fasting blood sample to measure thyroid hormone levels

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

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.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

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

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.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Zahedan University of Medical Sciences

**Street address**

Dr. Hasabi square

**City**

Zahedan

**Province**

Sistan-va-Balouchestan

**Postal code**

9816743463

**Approval date**

2022-10-24, 1401/08/02

**Ethics committee reference number**

IR.ZAUMS.REC.1401.300

**Health conditions studied****1****Description of health condition studied**

Subclinical iodine-deficiency hypothyroidism

**ICD-10 code**

E02

**ICD-10 code description**

Subclinical iodine-deficiency hypothyroidism

**Primary outcomes****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 Baniyan bio-fermentation company, made in Iran, is used. The synbiotic capsule will contain the following 7 freeze-dried probiotic strains. Lactobacillus casei, 2 x 10<sup>9</sup> CFU Lactobacillus acidophilus, 1.5 x 10<sup>9</sup> CFU Lactobacillus Rhamnosus, 2 x 10<sup>8</sup> CFU Lactobacillus bulgaricus, 2 x 10<sup>10</sup> CFU Bifidobacterium Breve, 7 x 10<sup>9</sup> 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

##### City

Zahedan

##### Province

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##### Postal code

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##### Phone

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##### Email

mrymp200@gmail.com

##### Web page address

<https://alihos.zaums.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Zahedan University of Medical Sciences

#### Full name of responsible person

Nourmohammad Bakhshani

#### Street address

Dr. Hasabi Square, Medical Sciences Pardis

#### City

Zahedan

#### Province

Sistan-va-Balouchestan

#### Postal code

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+98 54 3337 2151

#### Email

mrymp200@gmail.com

#### Web page address

<http://zaums.ac.ir>

#### 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

Internal Medicine

##### Street address

Danesh 23 Street

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##### Province

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## Person responsible for scientific 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**  
Internal Medicine

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Zahedan University of Medical Sciences

**Full name of responsible person**  
Maryam Pourmorteza

**Position**  
Resident

### Latest degree

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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