

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The Effect of Selenium Supplement on subclinical Hypothyroidism in children

Protocol summary

Study aim

Determination of the effect of selenium supplementation on serum T4 levels in children with subclinical hypothyroidism Determining the effect of selenium supplementation on serum TSH levels in children with subclinical hypothyroidism

Design

Clinical trial with control group with parallel, double-blind, randomized, phase 3 groups on 148 patients, Excel software rand function was used for randomization.

Settings and conduct

The study will be performed in Gorgan Endocrinology Clinic and Taleghani Pediatric Hospital based on subclinical hypothyroidism in children by examination. Patients will be randomly divided into two intervention and control groups and do not know the type of intervention received. Finally, after 3 months of receiving the drug, the two groups are evaluated by a specialist without knowing the type of patient group.

Participants/Inclusion and exclusion criteria

Children 3-16 years old Satisfaction to participate in the study With subclinical hypothyroidism (high TSH level and normal FT4 level and no medication)

Intervention groups

Children with subclinical hypothyroidism will be randomly assigned to one of two intervention or control groups. The intervention group will take one selenium supplement tablet containing 200 micrograms of selenium daily for 3 months. The control group will give the same placebo.

Main outcome variables

Evaluation of patient recovery using selenium supplementation based on TSH and T4 results

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220314054284N1**

Registration date: **2022-06-22, 1401/04/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-22, 1401/04/01**

Update count: **0**

Registration date

2022-06-22, 1401/04/01

Registrant information

Name

bahareh hooshyar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3232 0661

Email address

bahareh_hooshyar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Selenium Supplement on subclinical Hypothyroidism in children

Public title

The Effect of Selenium Supplement on subclinical

Hypothyroidism in children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Children with subclinical hypothyroidism Age 3- 16 years
Exclusion criteria:
Dissatisfaction with participating in the study Failure to follow the patient Lack of patient medication compliance by parents

Age
From **3 years** old to **16 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **148**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be assigned to experimental and control groups using the random block method. To perform randomization using quadruple blocks, first by throwing 16 regular hexagons 16 times, a random sequence of 16 quadruple blocks will be generated from the following blocks: AABB-ABAB-ABBA-BAAB-BABA-BBAA In the sequence, there will be 32 of each letter A and B. According to the above block, 64 envelopes will be prepared and in each envelope, the letter A or B will be placed and will be numbered from 1 to 64. The person delivering the envelopes to the patients does not know the letters inside. Randomization is done by a statistics and methodology consultant who does not have access to patients and only he knows what is in each envelope. Patients who received the letter A will be in the intervention group and patients who received the letter B will be in the control group

Blinding (investigator's opinion)
Double blinded

Blinding description
After randomly assigning the patients, the patient group and the control group will use the same drug (with the same packaging). After 3 months of receiving the drug, the patients will be evaluated by an endocrinologist who is not aware of the allocation.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of golestan University of Medical Sciences

Street address

at the beginning of Shast Kola Road,Hyrkan Boulevard,Basij Square

City

gorgan

Province

Golestan

Postal code

4934174515

Approval date

2022-03-17, 1400/12/26

Ethics committee reference number

IR.GOUMS.REC.1401.001

Health conditions studied

1

Description of health condition studied

Subclinical hypothyroidism

ICD-10 code

E02

ICD-10 code description

Subclinical iodine-deficiency hypothyroidism

Primary outcomes

1

Description

The amount of changes in the level of primary variables (TSH)

Timepoint

Sections for measuring thyroid hormone levels (TSH) before the intervention and 3 months after (as soon as the treatment period ends)

Method of measurement

Comparison of the effect of selenium supplementation on the reduction of TSH level

2

Description

The amount of changes in the level of primary variables (selenium)

Timepoint

Sections for measuring of selenium level before the intervention and 3 months after (as soon as the treatment period ends)

Method of measurement

Comparison of the effect of selenium supplementation on selenium changes

3

Description

The amount of changes in the level of primary variables of FT4

Timepoint

Sections for measuring of FT4 level before the intervention and 3 months after (as soon as the treatment period ends)

Method of measurement

Comparison of the effect of selenium supplementation on the reduction of T FT4 level

Secondary outcomes

1

Description

Changes in the body's metabolism

Timepoint

Before and 3 months after the start of the intervention

Method of measurement

Evaluation of weight, improvement of patient symptoms including constipation, fatigue, appetite, brittle nails and hair loss, etc.

Intervention groups

1

Description

Intervention group: Intervention group: In patients with subclinical hypothyroidism, levothyroxine treatment will be started after 3 to 6 months of follow-up. The treatment will be based on age and sex. Iran will be consumed once a day.

Category

Treatment - Drugs

2

Description

Control group: The main treatment (levothyroxine) for each placebo drug similar to the desired supplement containing starch will take one daily for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital and Gorgan Private Endocrinology Clinic

Full name of responsible person

Dr. Hossein Zaeri

Street address

Taleghani Children's Hospital, Janbazan Blvd., Fakhruddin Asad Gorgani Sq.,

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DR.ZAERI_ENDOCRINE@YAHOO.COM

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Honarvar

Street address

Vice Chancellor for Research, Golestan University of Medical Sciences, at the beginning of Shast Kola Road, Hyrkan Boulevard, Basij Square,

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Dr Hossein Zaeri

Position

Pediatric Endocrinology and Metabolism

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Third floor, Sarv building, Edalat 22 Ave, Valiasr St,
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Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr Hossein Zaeri

Position

Pediatric Endocrinology and Metabolism

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Person responsible for updating data

Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Bahareh Hooshyar

Position

Resident

Latest degree

Medical doctor

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

کل داده ها بالقوه پس از غیر قابل شناسایی کردن افراد قابل اشتراک
گذاری است

When the data will become available and for how long

Access period starts 6 months after the results are
published

To whom data/document is available

It will be available to researchers working in academic
and scientific institutions

Under which criteria data/document could be used

There are no special conditions.

From where data/document is obtainable

Dr. Hossein Zairi, Pediatric Endocrinologist Mobile
number: 09113554671 Office phone number:
01732320661 Office address: Gorgan, Valiasr St., 22
Adalat, Sarv Building, third floor Email:
dr.zaeri_endocrine @ YAHOO.COM

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

The applicant should provide his / her study file and the
purpose of receiving the data in the form of an email
with his / her research file (research plan), then after 3
months the file will be provided to the person.

Comments