

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effects of selenium supplementation on Thyroid gland size in Hashimoto's thyroiditis

Protocol summary

Study aim

The point of this study is finding out selenium effect on thyroid size in females with hashimoto thyroiditis. based on sonography indices

Design

Randomized double blinde, two arm parallel group, placebo and selenium taking groups are designed of 60 patients and followed for 3 months

Settings and conduct

patients who refer to endocrine clinic of Loghman Hakim hspital because of thyroid problem evaluate to enter the study. An endocrinologist is care provider and Outcome assessor of our research. He selects participants based on inclusion criteria and then phones to another investigator to determine participant code. In this trial we use selenium and placebo with same package ,color and shape with different cod based on table of random numbers .Then participant refers to one radiologist for thyroid sonography with their cod. after 3 month of treatment sonography and examination repeats and findings is recorded. the end of trial findigs are analysis just with codes. Thus Participant , care provider , outcome assessor and Data analyser are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: female, age 30_60 years, Anti TPO positive, $4 > \text{TSH} > .4$ mU/L, $0.25 < \text{Free T4} < .9$ pmol/L, goiter, 24 hours Urine Iodine > 100 microgram/L
Exclusion criteria: pregnancy, under treatment with Anti thyroid medicines, taking supplement contain of selenium

Intervention groups

Intervention is effect of selenium taking on thyroid size compared to placebo group by sonography findings in female with hashimoto thyroiditis

Main outcome variables

thyroid size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180510039601N1**

Registration date: **2018-06-02, 1397/03/12**

Registration timing: **retrospective**

Last update: **2018-06-02, 1397/03/12**

Update count: **0**

Registration date

2018-06-02, 1397/03/12

Registrant information

Name

Zohreh Maghsoomi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 5246

Email address

maghsoomi.z@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2013-09-06, 1392/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of selenium supplementation on Thyroid gland size in Hashimoto's thyroiditis

Public title

selenium in Hashimoto

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

female age 30_60 years Anti TPO positive 4>TSH >.4 mU/L 0.25<Free T4<.9 pmol/L goiter 24 hours Urine Iodine >100 microgram/L

Exclusion criteria:

pregnancy under treatment with Anti thyroid medicines taking supplement contain of selenium

Age

From **30 years** old to **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

individual unit, simple randomization with table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

in this trial we use selenium and placebo with same package ,color and shape with different cod based on table of random numbers . An endocrinologist is care provider and Outcome assessor of research. He selects participants based on inclusion criteria and then phones to another investigator to determine participant code.then participant refers to one radiologist for thyroid sonography with their cod. after 3 month of treatment sonography and examination repeats and findings is recorded. the end of trial findigs are analysis just with codes. Thus Participant , care provider , outcome assessor and Data analyser are blinded.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2013-02-24, 1391/12/06

Ethics committee reference number

131

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

Autoimmune thyroiditis,

ICD-10 code

E06.3

ICD-10 code description

Autoimmune thyroiditis

2**Description of health condition studied**

Nontoxic goiter, unspecified

ICD-10 code

E04.9

ICD-10 code description

Nontoxic goiter, unspecified

Primary outcomes**1****Description**

Thyroid size (Length x width x Anterior posterior diameters $\times \pi / 6$)

Timepoint

thyroid size(Length x width x Anterior posterior diameters $\times \pi / 6$) before and 3 month after intervention by sonography

Method of measurement

sonography

Secondary outcomes**1****Description**

Anti TPO level

Timepoint

AntiTPO measured before and 3 month after intervention

Method of measurement

labratory

Intervention groups**1****Description**

Intervention group: selenium Tablet, 200 micro gram, once daily, per Oral , for three months, From Century 21 company

Category

Treatment - Drugs

2**Description**

Control group: placebo once daily, per Oral , for three months

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Loghman Hakim Hospital

Full name of responsible person

Dr. Saeid Kalbasi

Street address

Makhsoos St, South Karegar Ave,

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1545913187

Phone

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loghman.hospital@sbmu.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Doctor Hosein Gudarzi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

private

Proportion provided by this source

60

Public or private sector

Private

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**

Iran University of Medical Sciences

Full name of responsible person

Zohreh Maghsoomi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

IPD collected for the primary outcome measure only

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

this only available for people working in academic institutions

Under which criteria data/document could be used

From where data/document is obtainable

email address: maghsoomi.z @iums.ac.ir

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

Comments