

# 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,

**City**

Tehran

**Province**

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**Postal code**

1545913187

**Phone**

+98 21 5541 9005

**Email**

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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Intl\_office@sbmu.ac.ir

**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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**Postal code**

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Saeid Kalbasi

**Position**

Associate professor

**Latest degree**

Subspecialist  
**Other areas of specialty/work**  
Internal Medicine  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Alborz university medical science  
**Full name of responsible person**  
Mojdeh Moghadasi  
**Position**  
Internist  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Internal Medicine  
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**Postal code**  
—  
**Phone**

+98 26 3420 4261

**Email**  
majhgol.mailbox@gmail.com

## 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