

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Effects of a 3 months treatment with selenium on serum Anti TPO level in patients with Hashimoto's thyroiditis compared with placebo

#### Protocol summary

2017-09-24, 1396/07/02

#### Summary

The aim of this study is to investigate the effect of selenium in patients with subclinical or clinical hypothyroidism induced by Hashimoto's thyroiditis under treatment with levothyroxine. The study population will be chosen from patients with hypothyroidism that refer to Yazd University of Medical Sciences clinics (Imam Ali Clinic and Khatam Al-Anbia Clinic). The patients are divided in two groups including selenium and placebo (simple randomized method). Inclusion criteria: Positive Anti TPO; Age between 15-50 years; Lack of kidney and liver disorder; lack of hyperthyroidism; not pregnancy; and Exclusion criteria: company dissatisfaction with the study; irregular drug use (no more than 20% of anticipated medications); patient's desire for each Time to leave the study. The sample size was calculated according on the means comparison formula which was 52 patients (26 in the intervention group and 26 in the placebo group). Initially, all patients with levothyroxine will be treated to keep the TSH level within the range of 0.3-5.1. Patients are then evaluated for anti TPO, T4, T3, and TSH. In the intervention group, for a period of three months, selenium 200 µg once daily administered with levothyroxine. The serum levels of thyroid hormones are listed and the clinical status of the patients is recorded and compared at the beginning and the end of the study.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016040918858N3**

Registration date: **2017-09-24, 1396/07/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

#### Registrant information

##### Name

Masoud Rahmanian

##### Name of organization / entity

Diabet Research Center, Yazd Shahid Sadughi  
University Of Mdcal Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 1728 0215

##### Email address

rahmanian@ssu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Yazd University of Medical Sciences

#### Expected recruitment start date

2015-03-20, 1393/12/29

#### Expected recruitment end date

2016-10-06, 1395/07/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effects of a 3 months treatment with selenium on serum Anti TPO level in patients with Hashimoto's thyroiditis compared with placebo

#### Public title

Effects of a 3 months treatment with selenium on serum Anti TPO level in patients with Hashimoto's thyroiditis compared with placebo

#### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Positivite Anti TPO; Age between 15-50 years; Lack of kidney and liver disorder; lack of hyperthyroidism; not pregnancy; Exclusion criteria: company dissatisfaction with the study; irregular drug use (no more than 20% of anticipated medications); patient's desire for each Time to leave the study

## Age

From **15 years** old to **50 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **52**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

Sealed envelops

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Diabetes Research Center,Yazd University of Medical Sciences

##### Street address

Yazd Diabet Research Center, Talar Honar, Bahonar to Azadi Square, Shahid Sadughi Blvd, Yazd

##### City

yazd

##### Postal code

#### Approval date

2015-02-04, 1393/11/15

#### Ethics committee reference number

240139

## Health conditions studied

### 1

#### Description of health condition studied

hashimoto's thyroiditis

#### ICD-10 code

E06.3

## ICD-10 code description

Autoimmune thyroiditis

## Primary outcomes

### 1

#### Description

Anti TPO

#### Timepoint

Before intervention and three months after intervention

#### Method of measurement

Laboratory kit-international units per ml

### 2

#### Description

TSH

#### Timepoint

Before intervention and three months after intervention

#### Method of measurement

Laboratory kit-international units per ml

### 3

#### Description

T3

#### Timepoint

Before intervention and three months after intervention

#### Method of measurement

Laboratory kit-Nanograms per deciliter

### 4

#### Description

T4

#### Timepoint

Before intervention and three months after intervention

#### Method of measurement

Laboratory kit-Micrograms per deciliter

### 5

#### Description

Age

#### Timepoint

Before intervention

#### Method of measurement

Years

### 6

#### Description

Sex

#### Timepoint

Before intervention

#### Method of measurement

sex

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Treatment with 200µg selenium pills once daily for 3 months+ Levothyroxin

### Category

Treatment - Drugs

2

### Description

control group: Treatment with placebo once daily for 3 months+levothyroxin

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Emam Ali Clinic, Yazd, Shahid Sadoughi University of Medical Sciences, Yazd

#### Full name of responsible person

Dr. Masoud Rahmanian

#### Street address

Navab Safavi Street

#### City

Yazd

2

### Recruitment center

#### Name of recruitment center

Yazd Khatamolanbia Clinic, Shahid Sadoughi University of Medical Sciences, Yazd

#### Full name of responsible person

Dr. Masoud Rahmanian

#### Street address

Taleghani stree

#### City

Yazd

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Yazd medical sciences University

#### Full name of responsible person

Masoud Rahmanian

#### Street address

Yazd-Shahid Sadoughi Bolvar-Bahonar Squer-Talar Honar st

#### City

Yazd

#### Grant name

#### Grant code / Reference number

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

Yes

### Title of funding source

Yazd medical sciences University

### Proportion provided by this source

100

### Public or private sector

empty

### Domestic or foreign origin

empty

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Diabet Research Center, Yazd Shahid Sadoughi University Of Mdical Science

#### Full name of responsible person

Somaye Gholami

#### Position

researcher

#### Other areas of specialty/work

#### Street address

Yazd diabetes research center, Talar Honar alley, shaheed sadoughi street, Yazd

#### City

Yazd

#### Postal code

#### Phone

+98 35 3728 0215

#### Fax

+98 37280216

#### Email

somayegholami90@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Yazd Diabet Research Center

#### Full name of responsible person

Masoud Rahmanian

#### Position

Endocrinologist

#### Other areas of specialty/work

#### Street address

Yazd Diabetes Research Center, Art Hall Square, towards Azadi Square, Bahonar Square, Shahid Sadoughi Boulevard, Yazd

#### City

Yazd

#### Postal code

#### Phone

+98 35 3728 0228

**Fax**

**Email**

Rahmanian@ssu.ac.ir

Drmasoudrahmanian@yahoo.com

**Web page address**

+98 35 3728 0228

**Fax**

**Email**

Rahmanian@ssu.ac.ir

Drmasoudrahmanian@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Diabet Research Center, Yazd Shahid Sadughi

University Of Mdicl Science

**Full name of responsible person**

Masoud Rahmanian

**Position**

Endocrinologist

**Other areas of specialty/work**

**Street address**

Yazd diabetes research center, Talar Honar alley,  
shaheed sadoughi street, Yazd

**City**

Yazd

**Postal code**

**Phone**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*