

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

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd Diabet Research Center

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Position

Endocrinologist

Other areas of specialty/work

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Person responsible for updating data

Contact

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University Of Mdicl Science

Full name of responsible person

Masoud Rahmanian

Position

Endocrinologist

Other areas of specialty/work

Street address

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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