

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of selenium on anti TPO Ab in autoimmune hypothyroid patients

Protocol summary

Study aim

Determine the effect of selenium on goiter & anti TPO Ab in autoimmune hypothyroid patients

Design

parallel group, double blind, randomized controlled trial

Settings and conduct

In Ghaem Hospital Endocrine Clinic, the patients were examined and according to the blood test results of the patients and the physical examination, the patients were randomly assigned to two groups. Only patients were not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: hypothyroid patients who did not received thyroid Hormon since 3 month ago that referred to endocrinology clinic of Ghaem hospital Exclusion criteria: Acute Systemic Symptoms, Renal failure, Hepatic failure , Malabsorption illness, Use of Selenium Supplements over the past 6 months

Intervention groups

selenium group 200 mcg /ml selenium capsule for a period of 3 months & 100 mg/ml Levothyroxin made in USA Nature Made control group plasebo capsule for a period of 3 months & 100 mg/ml Levothyroxin made in USA Nature Made

Main outcome variables

anti TPO Ab

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180504039518N1**

Registration date: **2018-08-12, 1397/05/21**

Registration timing: **retrospective**

Last update: **2018-08-12, 1397/05/21**

Update count: **0**

Registration date

2018-08-12, 1397/05/21

Registrant information

Name

Zohreh Jahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3622 6618

Email address

Jahaniz901@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-07-06, 1397/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of selenium on anti TPO Ab in autoimmune hypothyroid patients

Public title

The effect of selenium on anti TPO Ab in autoimmune hypothyroid patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

autoimmune hypothyroid patients who did not received thyroid Hormon since 3 month ago that referred to

endocrinology clinic of Ghaem hospital

Exclusion criteria:

Acute Systemic Symptoms Renal failure Hepatic failure
Malabsorption illness Use of Selenium Supplements over
the past 6 months

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization, prepared a list of all permutations for the block size. selected one of them and based on arrangement allocated participants to a treatment and control groups with sealed envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

patients, researchers and clinical personnel not aware from belonging to the each of the two groups with drug and placebo coding.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

University of Mashhad- next to Hiva Cinema -
Mashhad University of Medical Sciences- Deputy of
Research & Technology University -

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Approval date

2015-10-28, 1394/08/06

Ethics committee reference number

IR.MUMS.REC.1394.533

Health conditions studied

1

Description of health condition studied

autoimmune hypothyroidism

ICD-10 code

E03.8

ICD-10 code description

Other specified hypothyroidism

Primary outcomes

1

Description

Anti Thyroid Peroxidase

Timepoint

Before intervention, three months after intervention

Method of measurement

Electroluminescence Luminescence (ECL)

Secondary outcomes

1

Description

TSH

Timepoint

Before Intervention and 3 month after intervention

Method of measurement

Elisa kit lab

2

Description

Free T4

Timepoint

Before Intervention and 3 month after intervention

Method of measurement

Elisa kit lab

Intervention groups

1

Description

Intervention group: Take 200 Mcg selenium capsule per day for three months,the company that Manufactured it is Nature Made/USA and Take 100Mcg Levothyroxin per day that Manufactured by Iran Hormoune

Category

Treatment - Drugs

2

Description

Control group: placebo(Wheat bran),similar capsules with selenium capsules and no effective ingredients, the

company that Manufactured it is Mashhad
Pharmaceutical Faculty and Take 100Mcg Levothyroxin
per day that Manufactured by Iran Hormoune

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

zahra mazloum khorasani

Street address

Central Building of Mashhad University of Medical
Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3801 2976

Fax

+98 51 3840 6757

Email

mazloumz@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr mohsen tafaghodi

Street address

Central Building of Mashhad University of Medical
Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3841 2081

Email

vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

zahra jahani

Position

MD

Latest degree

Master

Other areas of specialty/work

Internal Medicine

Street address

Central Building of Mashhad University of Medical
Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 538012976

Email

jahaniz901@mums.ac.ir

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

zahra mazloum khorasani

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Ghaem Hospital, Parastar street, Ahmad abad Blvd,
Mashhad

City

mashhad

Province

Razavi Khorasan

Postal code

91766-99199

Phone

+98 915 109 8005

Email
mazloumz@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
zara mazloum khorasani
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Ghaem Hospital, Parastar Street, Ahmad Abad Blvd,
Mashhad
City
mashhad
Province
Razavi Khorasan
Postal code

91766-99199

Phone
+98 915 109 8005

Email
mazloumz@mums.ac.ir

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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available