

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of selenium therapy on primary autoimmune hypothyroidism: a randomized clinical trial

Protocol summary

Summary

Objective: to assess the effect of selenium therapy on primary autoimmune hypothyroidism Design: randomized controlled trial Setting: the eligible patients with primary autoimmune hypothyroidism who refer to endocrinology clinic of Shahid Beheshti hospital in 2012 will be enrolled Inclusion criteria: (a) age of 18 to 75 years; (b) having primary autoimmune hypothyroidisms; (c) having anti-TPO >200 U/ml Exclusion criteria: (a) history of Thyroid surgery; (b) history of thyroid cancer; (c) hypothyroidism resulted from hyperthyroidism; (d) history of auto-immune disease and known rheumatologic diseases; (e) pregnancy; (f) renal failure; (g) subclinical hypothyroidism; (h) history of using radioactive iodine, anti thyroid medication, cytotoxic; immunosuppressive, glucocorticoid, amiodaron, lithium, interferon, and chemotherapy Intervention: 20 patients with primary autoimmune hypothyroidism will receive levothyroxine plus selenium tablet 200 microgram once a day for three months Control: 20 patients with primary autoimmune hypothyroidism will receive levothyroxine only for three months Primary outcome: measurement of anti-TPO titer after three months Secondary outcome: measurement of (a) TSH, T3 and T4 titers after three months; (b) any adverse effect such as dizziness, abdominal pain, tremor, sweating, hair loss, sensation of smell of garlic

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211239014N13**
Registration date: **2012-12-01, 1391/09/11**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-12-01, 1391/09/11

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of selenium therapy on primary autoimmune hypothyroidism: a randomized clinical trial

Public title

Effect of selenium therapy on primary autoimmune hypothyroidism: a randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) age of 18 to 75 years; (b) having primary autoimmune hypothyroidisms; (c) having anti-TPO >200 U/ml Exclusion criteria: (a) history of Thyroid surgery; (b) history of thyroid cancer; (c) hypothyroidism resulted from hyperthyroidism; (d) history of autoimmune disease and known rheumatologic diseases; (e) pregnancy; (f) renal failure; (g) subclinical hypothyroidism; (h) history of using radioactive iodine, anti thyroid medication, cytotoxic; immunosuppressive, glucocorticoid, amiodaron, lithium, interferon, and chemotherapy

Age

From **14 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Local human subject review board

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave.

City

Hamadan

Postal code

6517838695

Approval date

2012-11-22, 1391/09/02

Ethics committee reference number

D-P-35-9-3040

Health conditions studied

1

Description of health condition studied

Primary autoimmune hypothyroidism

ICD-10 code

E06.3

ICD-10 code description

Autoimmune thyroiditis

Primary outcomes

1

Description

Measurement of anti-TPO titer

Timepoint

After three months

Method of measurement

Through electrochemiluminescence using diasorin set and liaison kit

Secondary outcomes

1

Description

TSH

Timepoint

3 months post intervention

Method of measurement

Laboratory

2

Description

T3

Timepoint

3 months post intervention

Method of measurement

Laboratory

3

Description

T4

Timepoint

3 months post intervention

Method of measurement

Laboratory

4

Description

abdominal pain

Timepoint

3 months post intervention

Method of measurement

With question

5

Description

hair loss

Timepoint

3 months post intervention

Method of measurement

With question

6**Description**

dizziness

Timepoint

3 months post intervention

Method of measurement

With question

7**Description**

sensation of garlic smell

Timepoint

3 months post intervention

Method of measurement

With question

8**Description**

tremor

Timepoint

3 months post intervention

Method of measurement

With question

9**Description**

sweating

Timepoint

3 months post intervention

Method of measurement

With question

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

20 patients with primary autoimmune hypothyroidism will receive levothyroxine plus selenium tablet 200 microgram once a day for three months

Category

Treatment - Drugs

2**Description**

20 patients with primary autoimmune hypothyroidism will receive levothyroxine only for three months

Category

Other

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

Shahid Beheshti hospital

Full name of responsible person

Dr Mayam Vasheghani

Street address

Eram Ave. Shahid Beheshti hospital

City

Hamadan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for Research the Technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr Heidar Tavilani

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan

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

Yes

Title of funding source

Vice chancellor for Research the Technology, Hamadan University of Medical Sciences

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**

Research Center for Health Sciences and Department of Epidemiology & Biostatistics

Full name of responsible person

Dr Jalal Poorolajal

Position

Assistant Professor of Epidemiology

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Research Center for Health Sciences and Department of Epidemiology & Biostatistics
Full name of responsible person
Dr Jalal Poorolajal
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Assistant Professor of Epidemiology
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Person responsible for updating data

Contact

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