Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 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

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Jalal Poorolajal
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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 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

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
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Person responsible for scientific inquiries

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Research Center for Health Sciences and Department of Epidemiology & Biostatistics

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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