

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Effect of treatment with Selenium and Vitamin C in comparison to placebo on serum level of anti-thyroid peroxidase antibody in patients with Hashimoto, thyroiditis, a clinical trial

Protocol summary

Summary

This single blind clinical trial will be done in Kavar, east of Shiraz, with the aim of determination of the effect of treatment with Selenium and Vitamin C on anti-thyroid peroxidase antibody titer in patients with Hashimoto thyroiditis. Participants will be selected from another previous study in this area which conducted by Research Vice-Chancellor of Shiraz University of Medical Sciences. In that survey blood samples of Kavar residents were taken for different measurements including thyroid function test and anti-thyroid peroxidase antibody titer. According to their test results 84 persons will be selected by simple random sampling method. Inclusion criteria will include: age, 15 years old or more; anti-thyroid peroxidase antibody titer 200 units per liter or more. Exclusion criteria will include: pregnant women; previous history of thyroid disorders; previous history of hypothalamo-hypophyseal disorders; presence of nonthyroidal disorders (such as renal; hepatic and; cardiovascular disorders; diabetes mellitus; etc); consumption of drugs with effect on thyroid hormones metabolism; consumption of sex hormones; glucocorticoids; vitamins or supplements. The participants will be divided in three groups randomly, each group will include 28 subjects. One group will be treated with Selenium 200 microgram tablet daily, the second group will be treated with Vitamin C 500 milligram tablet daily, and the last group will receive one tablet of placebo daily for 3 to 6 months. Before and after completion of treatment period thyroid function test and titer of anti-thyroid peroxidase antibody will be checked for them

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013092014717N1**

Registration date: **2015-05-13, 1394/02/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-13, 1394/02/23

Registrant information

Name

Fariba Karimi

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Vice-Chancellor of Shiraz University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of treatment with Selenium and Vitamin C in comparison to placebo on serum level of anti-thyroid peroxidase antibody in patients with Hashimoto, thyroiditis, a clinical trial

Public title

The effect of Selenium and Vitamin C for treatment of Hashimoto thyroiditis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age, 15 years old or more; anti-thyroid peroxidase antibody titer 200 units per liter or more.

Exclusion criteria: pregnant women; previous history of thyroid disorders; previous history of hypothalamo-hypophyseal disorders; presence of nonthyroidal disorders (such as renal; hepatic; cardiovascular disorders; diabetes mellitus; infectious diseases; renal stone; etc) ; consumption of drugs with effect on thyroid hormones metabolism; consumption of sex hormones; glucocorticoids; vitamins or supplements

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Department of Vice-Chancellor of Research of Shiraz University of Medical Sciences, 7th Floor, Central Building of Shiraz University of Medical Science, Zand Street, Shiraz, Iran

City

Shiraz

Postal code

7134814336

Approval date

2012-06-14, 1391/03/25

Ethics committee reference number

۷۵۷۱/۰۴/۹/ص/۹۲/پ

Health conditions studied

1

Description of health condition studied

Hashimoto thyroiditis

ICD-10 code

E06.3

ICD-10 code description

Autoimmune thyroiditis

Primary outcomes

1

Description

Titer of anti-thyroid peroxidase antibody

Timepoint

Before and after 3 to 6 months of treatment

Method of measurement

Measurement of anti-thyroid peroxidase antibody titer in serum by radioimmunoassay method

Secondary outcomes

1

Description

Thyroid function test including: thyroxine, triiodothyronine, and thyroid stimulating hormone levels

Timepoint

Before treatment and after completion of treatment course

Method of measurement

Measurement of serum levels of hormones by immunoradiometric assay method

Intervention groups

1

Description

The first intervention group will receive Selenium 200 micrograms tablet daily by mouth, for 3 to 6 months. Selenium tablets will be prepared from Sodium Selenate from Merck company by Shiraz school of pharmacy. The tablets will be similar to the tablets of the other two groups

Category

Treatment - Drugs

2

Description

The second intervention group will receive 500 milligrams tablet of Vitamin C daily, by mouth, for 3 to 6 months. Vitamin C tablets will be prepared by Avicenna company

Category

Treatment - Drugs

3**Description**

The control group will receive one tablet of placebo which will contain starch and will be similar to the real drugs. The placebo tablets will be prepared by Shiraz school of pharmacy

Category

Treatment - Drugs

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

Kavar Health Center, dependent to Shiraz University of Medical Sciences

Full name of responsible person

Dr. Fariba Karimi

Street address

Kavar Health Center dependent to Shiraz University of Medical Sciences, Kavar, Shiraz, Iran

City

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

Research Vice-Chancellor of Shiraz University of Medical Sciences

Full name of responsible person

Dr. Basyr Hashemi

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Department of Vice-Chancellor of Research of Shiraz University of Medical Sciences, 7th Floor, Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran

City

Shiraz

Grant name**Grant code / Reference number**

CT-P-91-3100

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

Yes

Title of funding source

Research Vice-Chancellor of Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Fariba Karimi

Position

Internist with subspecialty in Endocrinology and Metabolism, Assistant professor of Shiraz University

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Name of organization / entity

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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