Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of vitamin C supplementation on thyroid function in patients with primary hypothyroidism

Protocol summary

Summary

This study is a clinical trial to determine the effect of vitamin C supplementation on thyroid function in patients with primary hypothyroidism of both sexes between 18-75 years old, under treatment of oral levothyroxine. Patients with TSH levels between 0.5 to 4.5 micrograms per liter and take certain levothyroxine dose for at least 6 months of the study without any changes will study but patients with thyroid cancer, pregnant or nursing, taking OCP or estrogen and testosterone during 3 months ago and chronic gastrointestinal diseases will be excluded. Patient will treat with certain brand of levothyroxine sodium. At first Levels of fasting TSH, T4, T3 will be measured and recorded. Patients will treat with levothyroxine for 8 weeks and then the level of TSH, T4, T3 will be measured and recorded. Then the patients will treat with levothyroxine plus 500 mg vitamin C daily, at morning when pateints are fast, with 200 cc of water. After 8 weeks, thyroid function will be checked. All tests will be done in certain labratory. Results in patients before and after the end of treatment will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015102124634N1**
Registration date: **2016-05-31, 1395/03/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-05-31, 1395/03/11

Registrant information

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Name of organization / entity

Arak University of Medical Sceinces

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Recruitment status

Recruitment complete

Funding source

Research Department Arak University of Medical Sciences

Expected recruitment start date

2015-03-16, 1393/12/25

Expected recruitment end date

2016-06-14, 1395/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin C supplementation on thyroid function in patients with primary hypothyroidism

Public title

The effect of vitamin C on thyroid function

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: TSH level between 0.5 and 4.5 micrograms per liter; taking levothyroxine dose for at least 6 months without changes. Exclusion criteria: thyroid cancer; pregnant or nursing; taking OCP or estrogen and testosterone during 3 months ago; chronic GI disease.

Age
From **18 years** old to **75 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **73**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Alamolhoda, Maskan, Arak
City
Arak
Postal code
Approval date
2014-10-17, 1393/07/25
Ethics committee reference number
93-176-3

Health conditions studied

1

Description of health condition studied
Primary hypothyroidism
ICD-10 code
E03.8, E03
ICD-10 code description
Other specified hypothyroidism, Hypothyroidism, unspecified

Primary outcomes

1

Description
T3, T4
Timepoint
Arrival, 8 weeks after treatment
Method of measurement
In ng / dl using a blood test

Secondary outcomes

1

Description
TSH
Timepoint
Arrival, 8 weeks after treatment
Method of measurement
In U/ml using a blood test

Intervention groups

1

Description
8 weeks treatment with levothyroxine dose control with the Company, iran hormone and 8 weeks treatment with levothyroxine plus 500 milligrams of vitamin C daily morning fasting in the 200 cc model manufactured by water
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak AmirAlmomenin Hospital
Full name of responsible person
Dr. Kazemzad Hamid
Street address
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research Arak University of Medical Sciences
Full name of responsible person
Dr. Mohammad Rafiee
Street address
School of Medicine, Arak
City
Arak
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 Arak 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

Arak University of Medical sceinces

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Position

Assistant Internal Medicine

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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