

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Effect of vitamin C and levothyroxine on thyroid function in patients with primary hypothyroidism

Protocol summary

Study aim

We aim to evaluate the effects of vitamin C with levothyroxine on thyroid function in patients with primary hypothyroidism.

Design

In this research, 189 patients primary hypothyroidism with inclusion criteria and not having exclusion criteria referring to endocrinology clinics will be included. Patients will be randomly allocated to three groups receiving levothyroxin alone or with 500 mg or 1000 mg vitamin C and each patient will be given a specific code.

Settings and conduct

After patients selection, they will be randomly allocated to Levothyroxin daily alone or with 500 mg or 1000 mg vitamin C daily. Patients in all three groups will be treated for 8 weeks and will be evaluated before and after intervention for T4, TSH and T3 levels.

Participants/Inclusion and exclusion criteria

inclusion criteria: The age of 18 to 75 years of both sexes, The level of patient's TSH when entering the study is between 0.5 and 4.5 Miu / l, at least six months, the patient's dose of levothyroxine has not changed.

Exclusion criteria: Patients with thyroid cancer, chronic gastrointestinal, pulmonary, renal and hepatic (cirrhosis) diseases, history of kidney stones, heart failure, pregnant, lactating and purpose to pregnancy women, hormone-treated patients over the past three months P

Intervention groups

Patients in all three groups will receive levothyroxin with 500 mg or 1000 mg vitamin C or no vitamin C.

Main outcome variables

The main outcomes of the study are change in levels of T4, TSH and T3.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180220038807N1**

Registration date: **2018-05-30, 1397/03/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-30, 1397/03/09**

Update count: **0**

Registration date

2018-05-30, 1397/03/09

Registrant information

Name

mojtaba Alipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3313 6055

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-05, 1397/02/15

Expected recruitment end date

2018-08-06, 1397/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin C and levothyroxine on thyroid function in patients with primary hypothyroidism

Public title

Vitamin C with levothyroxine in primary hypothyroidism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The age of 18 to 75 years of both sexes is male and female The level of patient's TSH when entering the study is between 0.5 and 4.5 Miu / l At least six months, the patient's dose of levothyroxine has not changed

Exclusion criteria:

Patients with thyroid cancer, chronic gastrointestinal diseases, celiac disease, lactose intolerance, intestinal infections (Giardia lamblia), chronic lung, kidney and liver disease (cirrhosis), kidney stones, or history of kidney stones, CHF, vitamin B12 deficiency, pancreatic insufficiency As well as patients with jejunostyle or jejunioileal bypass, suffering from short-systolic syndrome or autoimmune gasteritis and H.Pylori infection Pregnant, lactating and purpose to pregnancy women Hormone-treated patients, such as taking contraceptives or estrogen and testosterone over the past three months Patients treated with any of the following drugs or compounds: ferrous sulfate, calcium carbonate, colestipol, aluminum hydroxide, sucralfate, propranolol, laxatives, levostatin, solvate ester (sevelamer), cromium picolinate, bile acid sequestrants Gastric acid antacids, sucralfate, sodium polysterone sulfonate, cholesterol, dopamine analogues, steroids, somatostatin and also anticonvulsants, raloxifene, cimetidine, amiodarone, sertraline and activated charcoal. Patients who have a change in their TSH for more than 1 unit in the first 8 weeks of their study or who have complications of vitamin C (severe nausea and vomiting or severe diarrhea)

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **189**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized into three groups using random number blocks and using sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and the person evaluating the treatment outcome will be blinded to the allocated groups.

Placebo

Not used

Assignment

Parallel

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

Arak University of Medical Sciences, Alam-ol-Hoda street, Shahid Shiroudi Ave.,

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2017-10-29, 1396/08/07

Ethics committee reference number

IR.ARAKMU.REC.1396.153

Health conditions studied

1

Description of health condition studied

Hypothyroidism

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Thyroid function test levels

Timepoint

Before and 8 weeks after intervention

Method of measurement

By measuring serum levels of TSH and T4

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients will receive levothyroxine 0.1 mg and vitamin C 1000 mg daily

Category

Treatment - Drugs

2

Description

Intervention group: Patients will receive levothyroxine 0.1 mg and vitamin C 1000 mg daily

Category

Treatment - Drugs

3

Description

Control group: Patients will receive levothyroxine 0.1 mg daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir-Almomenin Hospital

Full name of responsible person

Mojtaba alipour

Street address

Basij Square.,

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3848176941

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m.alipour@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Ali Arash Anoushrevani

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Mojtaba Alipour

Position

دستیار بیماری های داخلی

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Position

internal Medicine Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Position

Internal Medicine resident

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

No further information available

When the data will become available and for how long

No further information available

To whom data/document is available

No further information available

Under which criteria data/document could be used

No further information available

From where data/document is obtainable

No further information available

What processes are involved for a request to access data/document

No further information available

Comments