Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 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
m.alipour@arakmu.ac.ir

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 jejunoileal 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.,
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3601
Email
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 Anoushirevani
Street address
Arak University of Medical Sciences, Basij square
City
arak
Province
Markazi
Postal code
6941-7-38481
Phone
+98 86 3417 3638
Email
anoshirvaniAR@gmail.com
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
Street address
Amir-almomenin Hospital, Basij square.,
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3601
Email
m.alipour@arakmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mojtaba Alipour
Position
internal Medicine Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Basij square.,
City
Arak
Province
Markazi

Postal code
3848176941
Phone
+98 86 3417 3601
Fax
Email
m.alipour@arakmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mojtaba alipour
Position
Internal Medicine resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Basij square.,
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3601
Email
m.alipour@arakmu.ac.ir

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