Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of selenium on the size of thyroid nodules in euthyroid patients

Protocol summary

Study aim
Determine the effect of selenium on the size of thyroid nodules in patients with euthyroid
Design
parallel group, double blind, randomized controlled trial
Settings and conduct
Thyroid nodule sampling unit at Imam Reza Hospital In this medical study, which provided patients with medication (intravenous drug), the patients and the final evaluator of the outcomes of the project that performed the analysis, were not aware of the grouping of patients.
Participants/Inclusion and exclusion criteria
in clusion criteria: euthyroid Patients aged 20-65 years with thyroid nodules who have normal pathology. with thyroid nodule of more than 1 cm in size or a multidolateral goiter with a nodule greater than 1 cm, have normal cytology . serum selenium levels were within the normal range.exclusion criteria: If the patient is unsatisfied,Thyroid nodule diagnosed as suspected or malignant. pregnant or breastfeeding.
Intervention groups
200 mg / ml selenium capsule for a period of 3 months
Main outcome variables
Thyroid nodule size

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170710035001N2**
Registration date: **2018-05-16, 1397/02/26**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-16, 1397/02/26**
Update count: **0**
Registration date
2018-05-16, 1397/02/26

Registrant information
Name
ZEID ZEREHSAZ
Name of organization / entity
Mashhad University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source
State of Mashhad University of Medical Sciences

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
The effect of selenium on the size of thyroid nodules in euthyroid patients

Public title
The effect of selenium on the thyroid nodule
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
have a thyroid nodule measuring more than 1 cm in size or a multi nodular goiter with a nodule greater than 1 cm These patients should have normal cytology (in FNA thyroid) the serum levels of selenium should be in the

normal range

Exclusion criteria:

Pregnant women Thyroid nodule diagnosed as suspected or malignant in FNA If the patient is not satisfied with the continuation of the study, selenium intolerance

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization with seal packet

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients who obtaining informed consent were entered the study and randomly assigned to one of the two groups. patients, researchers and clinical personnel not aware from belonging to the each of the two groups with drug and placebo coding .

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Mashhad Holy, End of Shahid Fakoori Boulevard, between Shahid Javan Square and Shahid Al-Shahidi square, Zanjan Health

City

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Province

Razavi Khorasan

Postal code

9177899191

Approval date

2017-07-09, 1396/04/18

Ethics committee reference number

IR.MUMS.FM.REC.1396.05

Health conditions studied

1

Description of health condition studied

THYROID NODULE

ICD-10 code

E04.1

ICD-10 code description

E04.1-E04.9

Primary outcomes

1

Description

Thyroid nodule size

Timepoint

Before intervention, three months after intervention

Method of measurement

Sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Edible selenium capsule Use 200 micro grams per day for three months,Manufacturer of the century21 country of America

Category

Treatment - Drugs

2

Description

Control group: Taking placebo(Wheat bran),similar capsules with selenium capsules and no effective ingredients,Use 200 micro grams per day for three months,manufacturing factory:Mashhad Pharmaceutical Faculty

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr Masoud Mohebi, Assistant Professor of the University

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
dr mohsen tafaghodi
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University of Mashhad- next to Hiva Cinema - Mashhad University of Medical Sciences- Deputy of Research & Technology University -
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
masoud mohebbi
Position
Associate professor of endocrin and Adult Metabolism
Latest degree
Subspecialist
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Person responsible for updating data

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available