

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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 ZEREHSАЗ

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3724 5201

Email address

zerehsazz951@mums.ac.ir

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 Fakoory Boulevard,
between Shahid Javan Square and Shahid Al-Shahidi
square, Zanjan Health

City

MASHHAD

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

City

MASHHAD
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3840 6757
Email
ZerehsazZ951@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
dr mohsen tafaghodi
Street address
University of Mashhad- next to Hiva Cinema -
Mashhad University of Medical Sciences- Deputy of
Research & Technology University -
City
MASHHAD
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3840 6757
Email
ZerehsazZ951@mums.ac.ir

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
Other areas of specialty/work
Internal Medicine
Street address
Mashhad, Imam Reza Hospital
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3802 2358
Fax
Email
MohebbiM@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Masoud Mohebbi
Position
assisstant professor of endocrinology
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Emam Reza hospital ,internal medicine ward
City
mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3802 2370
Fax
Email
mohebbim@mums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
masoud mohebbi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Central Building of Mashhad University of Medical

Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City

Mashhad

Province

Razavi Khorasan

Postal code

9177899191

Phone

+98 51 3802 2358

Fax

Email

MohebbiM@mums.ac.ir

Web page address

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