Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of antithyroid drug therapy on bone mineral density of young women with endogenous subclinical hyperthyroidism

Protocol summary

Summary

There is a controversy about effect of treatment of subclinical hyperthyroidism (suppressed TSH with normal FT4 and FT3) on bone mineral density. This study investigates effects of treatment of subclinical hyperthyroidism with oral anti-thyroid drugs on bone mineral density of young (premenopausal) women that are at risk of postmenopausal osteoporosis. Thirty eligible patients referred to Kurdistan nuclear medicine center for thyroid function study, which have suppressed TSH and normal FT4 & FT3 will be selected. These patients shouldn't have any history of thyroid disorders or any cause of secondary osteoporosis. They are randomly divided into two groups of 15 patients. One group is treated with oral anti-thyroid drug (methimazole). Both treated and observed groups are followed for 1 year with periodic thyroid function testing. The treated group should be euthyroid and the observed group should stay with subclinical hyperthyroidism for 1 year. Bone mineral density of femoral neck and lumbar vertebrae are measured by DXA method in both groups at the beginning of the study and after 1 year. Changes in BMDs of the observed and treated groups after one year are compared to determine any statistically significant differences between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138809012750N1**
Registration date: **2010-05-11, 1389/02/21**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-05-11, 1389/02/21

Registrant information

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Siamak Derakhshan
Name of organization / entity
Kurdestan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Kurdistan university of medical sciences

Expected recruitment start date

2009-05-05, 1388/02/15

Expected recruitment end date

2010-05-05, 1389/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of antithyroid drug therapy on bone mineral density of young women with endogenous subclinical hyperthyroidism

Public title

Effects of antithyroid drug therapy on bone mineral density of young women with endogenous subclinical hyperthyroidism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Young women referred to Kurdistan nuclear medicine center for thyroid evaluation which has

suppressed TSH and normal FT4 and FT3 without history of thyroid disorders. Exclusion criteria: Secondary osteoporosis, hypersensitivity to oral anti-thyroid drugs, discontinuation of 1 year follow-up

Age
From **15 years** old to **55 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kurdistan medical university

Street address
Pasdaran boulevard-in front of Shadi hotel

City
Sanandaj

Postal code

Approval date
empty

Ethics committee reference number
668/پ/14/پ

Health conditions studied

1

Description of health condition studied
Subclinical hyperthyroidism

ICD-10 code
E05.9

ICD-10 code description
Thyrotoxicosis, unspecified Hyperthyroidism NOS

Primary outcomes

1

Description
Thyroid function

Timepoint
3-6-12 months after treatment

Method of measurement
TSH, freeT3, freeT4 measurement by IRMA & RIA methods

Secondary outcomes

1

Description
Bone mineral density

Timepoint
12 months after treatment or follow-up

Method of measurement
Measuring BMD of lumbar vertebrae(L2-L4) and femoral neck by DXA method

Intervention groups

1

Description
Intervention: Methimazole 5-10 mg/day po until the patient become euthyroid then 2.5-5 mg/day po maintenace dose for 1 year.

Category
Treatment - Drugs

2

Description
Control: Without any intervention for 1 year

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Kurdistan nuclear medicine center

Full name of responsible person
Siamak Derakhshan M.D

Street address
No.26 Golbarg alley Abidar avenue

City
Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kurdistan university of medical sciences

Full name of responsible person

Fardin Gharibi
Street address
Pasdaran boulevard,in front of Shadi Hotel
City
Sanandaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kurdistan 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
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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