

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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

Name

Siamak Derakhshan

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 1328 2532

Email address

siamak.derakhshan@muk.ac.ir

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 maintenance 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

Name of organization / entity

Kurdistan university of medical science

Full name of responsible person

Siamak Derakhshan M.D

Position

Nuclear medicine physician

Other areas of specialty/work

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Position

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Other areas of specialty/work

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Web page address

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