Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of monotherapy with L-levothyroxine compared to combination therapy with L-levothyroxine and L-triiodothyronine on lipid profile of hypothyroid patients

Protocol summary

Summary

Goal of study: The goal of this study is to compare various parameters in the patients with hypothyroidism who receiving Levothyroxine (L-T4) or combination therapy with Levothyroxine (L-T4) and L-Triiodothyronine (L_T3). Design: This study is a randomized, single blind, clinical trial. Inclusion criteria: New cases of hypothyroidism; Do not consumption of any thyroid hormones in the past three months Exclusion criteria: Use of any Anti depressant agents; OCP; Anti hyperlipidemic agents; Orliestat; Breast feeding and pregnancy; Opium addiction; Myxedema coma; Use of any drug that interfere with thyroid hormones metabolism; the Patients that registered for other studies in the last month; coronary artery disease Sample size: Seventy patients with hypothyroidism The patients will be divided in two groups, group A (35patients) will treated with Levothyroxine and group B (35 patients) will be treated with Levothyroxine and Triiodothyronine for 6 months. Intervention: We treat the patients in group (A) with levothyroxine 100 microgram per day and the patients in group (B) with Levothyroxine 75 microgram plus Liothyronine 12.5 microgram per day, orally. We will adjust the dose of Levothyroxine with the serum TSH level in each group. Levothroxine and Liothyronine tablets manufactured by Iran Hormone company. Intervention time: 6 months (December; 2013 – June; 2014) Primary outcome: Compare lipid profile, body mass index, quality of life and blood pressure in the monotherapy with Levothyroxine and combination therapy with Levothyroxine and Triiodothyronine in hypothyroid patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310204849N4**
Registration date: **2013-12-06, 1392/09/15**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-12-06, 1392/09/15

Registrant information

Name
Amir Ziaee

Name of organization / entity
Metabolic Diseases Research Center, Qazvin University of Medical Sciences, Qazvin, Iran

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Iran (Islamic Republic of)

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+98 28 1336 0084

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aziaee@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qazvin University of Medical Sciences

Expected recruitment start date

2013-12-11, 1392/09/20

Expected recruitment end date

2014-06-10, 1393/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the effect of monotherapy with L-levothyroxine compared to combination therapy with L-levothyroxine and L-triiodothyronine on lipid profile of hypothyroid patients

Public title
Evaluation of the combination therapy with L-levothyroxine and L-triiodothyronine in hypothyroid patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: New cases of hypothyroidism; Do not consumption of any thyroid hormones in the past three months Exclusion criteria: Use of any Anti depressant agents; OCP; Anti hyperlipidemic agents; Orliestat; Breast feeding and pregnancy; Opium addiction; Myxedema coma; Use of any drug that interfere with thyroid hormones metabolism; the Patients that registered for other studies in the last month; coronary artery disease

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences

Street address
Shahid Bahonar blvd, Vice chancellor for research, Qazvin University of Medical Sciences

City
Qazvin

Postal code

Approval date
2013-10-14, 1392/07/22

Ethics committee reference number
28/20/7920

Health conditions studied

1

Description of health condition studied
hypothyroidism

ICD-10 code
E00, E01,

ICD-10 code description
Disorders of thyroid gland

Primary outcomes

1

Description
Lipid profile

Timepoint
Before intervention and 12 and 24 weeks after the intervention

Method of measurement
quantitative detective kits in human serum or plasma with photometric method

2

Description
Body mass index

Timepoint
Before intervention and 12 and 24 weeks after the intervention

Method of measurement
weight (Kg)/ height(m)2

3

Description
Blood pressure

Timepoint
Before intervention and 12 and 24 weeks after the intervention

Method of measurement
Manometer

4

Description
Quality of life

Timepoint
Before intervention and 12 and 24 weeks after the intervention

Method of measurement
Questionnaire

5

Description

TSH

Timepoint

Before intervention and 12 and 24 weeks after the intervention

Method of measurement

Non competitive immunoradiometric assay (IRMA) for quantitative detection of TSH in human serum or plasma with gamma counter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Monotherapy with levothyroxine 100 microgram once daily for 24 weeks

Category

Treatment - Drugs

2

Description

Intervention group 2: Combination therapy with levothyroxine 75 microgram pluse triiodothyronine 12.5 microgram once daily for 24 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine Clinic of Velayat Hospital

Full name of responsible person

Street address

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qazvin University of Medical Sciences

Full name of responsible person

Dr. Saeed Asefzadeh

Street address

Shahid Bahonar blvd, Vice chancellor for research, Qazvin University of Medical Sciences

City

Qazvin

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Qazvin 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

Metabolic Diseases Research Center, Qazvin University of Medical Sciences, Qazvin, Iran

Full name of responsible person

Dr.Amir Ziaee

Position

Professor, Department of Endocrinology

Other areas of specialty/work

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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