

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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; Orlistat; 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

Country

Iran (Islamic Republic of)

Phone

+98 28 1336 0084

Email address

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; Orlistat; 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 Bamonar 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

Street address
Booali-Sina St. Booali-Sina Hospital, Qazvin Metabolic Diseases Research Center

City
Qazvin

Postal code

Phone
+98 28 1336 0084

Fax

Email
aziaee1963@yahoo.com, aziaee@qums.ac.ir

Web page address

Person responsible for scientific 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

Street address
Booali-Sina St. Booali-Sina Hospital, Qazvin Metabolic Diseases Research Center

City
Qazvin

Postal code

Phone
+98 28 1336 0084

Fax

Email

aziaee1963@yahoo.com, aziaee@qums.ac.ir

Web page address

+98 28 1336 0084

Fax**Email**

aziee1963@yahoo.com, aziaee@qums.ac.ir

Web page address**Person responsible for updating data****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**Street address**

Booali-Sina St. Booali-Sina Hospital, Qazvin Metabolic
Diseases Research Center

City

Qazvin

Postal code**Phone****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