

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 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 be 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)<sup>2</sup>

**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 plus 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

#### 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*