

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Comparing serum homocysteine value in patients with hypothyroidism who are treated with folic acid and Levothyroxine with patients who receive Levothyroxine

Protocol summary

Summary

The objective of this study was to assess the effect of combination of levothyroxine and folic acid on Homocysteine in patients with Hypothyroidism. In this double blind clinical trial study, a total of 60 patients with hypothyroidism who referred to Endocrine Clinics of Buali Hospital, Qazvin, Iran, were assigned into 2 groups. The patients in both groups were treated with 50-100 mg levothyroxine. The patients in the intervention group received folic acid (1mg/day), as well. The patients were visited every two months until being euthyroid, and Homocysteine level was measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010024849N1**

Registration date: **2010-10-29, 1389/08/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-10-29, 1389/08/07

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

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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

2009-03-21, 1388/01/01

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing serum homocysteine value in patients with
hypothyroidism who are treated with folic acid and
Levothyroxine with patients who receive Levothyroxine

Public title

Comparing serum homocysteine value in patients
treated with folic acid and Levothyroxine with patients
who receive Levothyroxine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: clinical signs of hypothyroidism,
TSH>10 mIU/L, normal function of kidney, not having
systemic diseases. Exclusion criteria: taking drugs such
as Phenobarbital, Phenytoin, Tamoxifen, Methotrexate,
Theophylline, having diabetes, anemia or other systemic
diseases, pregnancy, smoking

Age

No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qazvin University of Medical Sciences

Street address
Qazvin University of Medical Sciences

City
Qazvin

Postal code

Approval date
empty

Ethics committee reference number
28/20/3335

Health conditions studied

1

Description of health condition studied
Other hypothyroidism

ICD-10 code
E03.8

ICD-10 code description
Other specified hypothyroidism

Primary outcomes

1

Description
homosysteine level

Timepoint
after intervention

Method of measurement

micromole/litr

Secondary outcomes

1

Description
cardiovascular complications

Timepoint
after intervention

Method of measurement
micromole/litr

Intervention groups

1

Description
Levothyroxine, 50-100 mg/day as well as Folic acid, 1mg/day untill being euthyroid

Category
Treatment - Drugs

2

Description
Levothyroxine, 50-100 mg/day untill being euthyroid

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Endocrine Clinic of Buali 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 Assefzadeh

Street address
Qazvin

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**

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Amir Ziaee

Position

Endocrinologist/Associate professor

Other areas of specialty/work**Street address**

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Qazvin University of Medical Sciences

Full name of responsible person

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