Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of fasting versus bedtime levothyroxin on primary hypothyroidism: A randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of Effect of fasting versus bedtime levothyroxin on primary hypothyroidism. Design: A randomized clinical trial. Setting and conduct: All eligible patients with acute or chronic brucellosis who will refer to Shahid Beheshti Hospital during the study period will be enrolled in to the trial. Inclusion criteria: (a) patients with primary hypothyroiditis; (b) age of 18 years or older. Exclusion criteria: (a) history of cardiovascular disease; (b) being pregnant or plan to pregnant; (c) history of malabsorption or gastritis; (d) using drug reducing levothyroxine absorption such as aluminum or sucralfate. Intervention: Oral levothyroxine 1.6 mcgr per kg before sleep for 8 weeks. Control: Oral levothyroxine 1.6 mcgr per kg half an hour before breakfast for 8 weeks. Primary outcome: (a) response to treatment based on serum T4 level 8 months after treatment; (b) response to treatment based on serum TSH level 8 months after treatment. Secondary outcome: Probable systematic adverse effects such as nausea and vomiting through history taking 8 months after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406299014N38**
Registration date: **2014-07-04, 1393/04/13**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-07-04, 1393/04/13

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2014-07-23, 1393/05/01

Expected recruitment end date

2015-08-22, 1394/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of fasting versus bedtime levothyroxin on primary hypothyroidism: A randomized clinical trial

Public title

Effect of fasting versus bedtime levothyroxin on primary hypothyroidism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) patients with primary hypothyroiditis; (b) age of 18 years or older. Exclusion criteria: (a) history of cardiovascular disease; (b) being pregnant or plan to pregnant; (c) history of malabsorption or gastritis; (d) using drug reducing

levothyroxine absorption such as aluminum or sucralfate.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization: Using block randomization with group of four so that every four patents will be randomly assigned to either intervention or control groups. This process will be continued until to reach the sample size. Blinding: The type drug in intervention and control groups is the same but the time of using drug is different. Since, blinding the time of drug usage is impossible. Therefore, the trial will be run as open label.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Postal code
6517838695

Approval date
2014-06-25, 1393/04/04

Ethics committee reference number
D/P/16/35/9/1545

Health conditions studied

1

Description of health condition studied
primary hypothyroidism

ICD-10 code
E03.9

ICD-10 code description
Hypothyroidism, unspecified

Primary outcomes

1

Description
response to treatment

Timepoint
8 months after treatment

Method of measurement
based on serum T4 level

2

Description
response to treatment

Timepoint
8 months after treatment

Method of measurement
based on serum TSH level

Secondary outcomes

1

Description
Probable systematic adverse effects such as nausea and vomiting

Timepoint
8 months after treatment.

Method of measurement
through history taking

Intervention groups

1

Description
Oral levothyroxine 1.6 mcgr per kg before sleep for 8 weeks

Category
Treatment - Drugs

2

Description
Oral levothyroxine 1.6 mcgr per kg half an hour before breakfast for 8 weeks

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Farshchian Hospital
Full name of responsible person
Dr Bahareh Babeway
Street address
Farshchian Hospital, Mirzadeh Eshghi Ave.
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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Hamadan
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 the Technology, Hamadan 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
Farshchian Hospital
Full name of responsible person
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Person responsible for scientific inquiries

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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