

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

##### 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 patients 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

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Farshchian Hospital, Mirzadeh Eshghi Ave.

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bahareh.babeway@gmail.com

**Web page address****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**City**

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**

Dr Bahareh Babeway

**Position**

Resident of Internal Medicine

**Other areas of specialty/work****Street address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Farshchian Hospital

**Full name of responsible person**

Dr Mayam Vasheghani

**Position**

Internist

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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*