

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The Effect of Levothyroxine on Cardiac Function in Children with Subclinical Hypothyroidism

#### Protocol summary

##### Study aim

The Effect of Levothyroxine on Cardiac Function in Children with Subclinical Hypothyroidism

##### Design

Clinical trial without control group; the sample size includes all of the eligibility criteria that 30-sample are predictable, phase 2 clinical trial.

##### Settings and conduct

This clinical trial study was performed will be selected by an inhomogeneous method in Children aged 4-12 years with subclinical hypothyroidism referring to Amirkola Children's Hospital Endocrinology Clinic.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Children aged 4-12 years with subclinical, Exclusion Criteria: Obese children, Children with high blood pressure, Children who already use levothyroxine, Children with congenital or acquired heart disease proven and under medical treatment, Children with liver or kidney disease, Children with high blood lipids, Children with diabetes, Children with infectious diseases.

##### Intervention groups

Children aged 4 to 12 years who referred to the endocrinology clinic were diagnosed with subclinical hypothyroidism. Treatment with 0.1 mg levothyroxine tablets starts with hormones with a dose of 4 micrograms per kilogram per day, which will be used by the patients in the early hours of fasting.

##### Main outcome variables

LVSD , LVDD , FS , EF , E/E' ,MPI

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180228038900N3**

Registration date: **2018-12-02, 1397/09/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-12-02, 1397/09/11**

Update count: **0**

##### Registration date

2018-12-02, 1397/09/11

##### Registrant information

###### Name

Morteza Alihanpour Aghamaleki

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3234 6963

###### Email address

m.alijanpour@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-14, 1397/07/22

##### Expected recruitment end date

2019-10-14, 1398/07/22

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Levothyroxine on Cardiac Function in Children with Subclinical Hypothyroidism

##### Public title

The Effect of Levothyroxine on Cardiac Function in Children with Subclinical Hypothyroidism

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Diagnosis of subclinical hypothyroidism

**Exclusion criteria:**

Obese children Children with hypertension Children who already use levothyroxine Children with congenital or acquired heart disease proven and under medical treatment Children with liver or kidney disease Children with high blood lipids Children with diabetes Children with infectious diseases

**Age**

From **4 years** old to **12 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Single

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Babol University of Medical Sciences

**Street address**

Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences, Ganjafroz Street

**City**

Babol

**Province**

Mazandaran

**Postal code**

4717647745

**Approval date**

2018-10-14, 1397/07/22

**Ethics committee reference number**

IR.MUBABOL.HRI.REC.1397.153

**Health conditions studied**

1

**Description of health condition studied**

Hypothyroidism Subclinical

**ICD-10 code**

E01.2

**ICD-10 code description**

Iodine-deficiency-related (endemic) goitre, unspecified

**Primary outcomes**

1

**Description**

left ventricular end-systolic diameter

**Timepoint**

Before starting treatment

**Method of measurement**

Echocardiography

2

**Description**

left ventricular end-Dystolic diameter

**Timepoint**

Before starting treatment

**Method of measurement**

Echocardiography

3

**Description**

Fractional - Shortening

**Timepoint**

Before starting treatment

**Method of measurement**

Echocardiography

4

**Description**

Tissue Doppler echocardiography

**Timepoint**

Before starting treatment

**Method of measurement**

Echocardiography

5

**Description**

Ejection fraction

**Timepoint**

Before starting treatment

**Method of measurement**

Echocardiography

6

**Description**

Myocardial Perfusion Imaging

**Timepoint**

Before starting treatment

**Method of measurement**

Echocardiography

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: For patients, 0.1 mg levothyroxine tablets are prescribed by Iranian company Hormones with a dose of 4 micro/miligrams per day.

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Amirkola Children's Hospital

#### Full name of responsible person

Morteza Alijanpour Aghamaleki

#### Street address

Amirkola Children's Hospital, Street No. 19

#### City

Babol

#### Province

Mazandaran

#### Postal code

4731741151

#### Phone

+98 11 3234 6963

#### Fax

+98 11 3234 6963

#### Email

m.alijanpour@yahoo.com

#### Web page address

<http://amirkola.mubabol.ac.ir>

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Babol University of Medical Sciences

#### Full name of responsible person

Babol University of Medical Sciences

#### Street address

Vice- Chancellor for Research Technology Affairs,  
Babol University of Medical Sciences, Ganjafroz Street

#### City

Babol

#### Province

Mazandaran

#### Postal code

4717647745

#### Phone

+98 11 3219 7667

#### Email

[r.ghadimi@mubabol.ac.ir](mailto:r.ghadimi@mubabol.ac.ir)

#### Web page address

<http://www.mubabol.ac.ir/>

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Babol University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

empty

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Babol University of Medical Sciences

#### Full name of responsible person

Morteza Alihanpour Aghamaleki

#### Position

Assistant professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Pediatrics

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Amirkola Children's Hospital, Street No. 19

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#### Web page address

<http://amirkola.mubabol.ac.ir/>

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Babol University of Medical Sciences

#### Full name of responsible person

Morteza Alijanpour Aghamaleki

#### Position

Associatant professor

#### Latest degree

Subspecialist

**Other areas of specialty/work**

Pediatrics

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**Web page address**<http://amirkola.mubabol.ac.ir/>**Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Nasrin Bano Rupani

**Position**

Rezident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

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**Email**

rupani.nb17@gmail.com

**Web page address**<http://amirkola.mubabol.ac.ir>**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

-

**When the data will become available and for how long**

-

**To whom data/document is available**

Public access

**Under which criteria data/document could be used**

-

**From where data/document is obtainable**

Dr. Morteza Alijanpour

**What processes are involved for a request to access data/document**

Email as soon as possible.

**Comments**