

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of levothyroxine therapy in pregnant women with thyroid peroxides antibody on Pregnancy outcomes

#### Protocol summary

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#### Summary

This Single Blind RCT evaluates the treatment effects of levothyroxine on reducing pregnancy complications among pregnant women having such antibodies. The pregnant women having thyroid peroxides antibody are randomly divided into two groups. Up to the end of pregnancy period, a daily dose of 50 microgram levothyroxine is prescribed for interventions group. Control group will not receive any treatment. The participants are followed up till the end of pregnancy period and the pregnancy outcomes (Preterm delivery, Abortion and PROM) and embryonic consequences (Apgar and Weight) are assessed and compared between groups.

#### Recruitment status

**Recruitment complete**

#### Funding source

Kurdistan University of Medical Sciences

#### Expected recruitment start date

2010-02-20, 1388/12/01

#### Expected recruitment end date

2010-12-22, 1389/10/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT201105316152N2**

Registration date: **2011-06-19, 1390/03/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2011-06-19, 1390/03/29

#### Registrant information

#### Name

Fariba Seyedoshohadaei

#### Name of organization / entity

Kurdistan University of Medical Sciences

#### Country

Iran (Islamic Republic of)

#### Phone

+98 82 1328 2001

#### Email address

#### Scientific title

Effect of levothyroxine therapy in pregnant women with thyroid peroxides antibody on Pregnancy outcomes

#### Public title

Effect of levothyroxine therapy in pregnant women with thyroid peroxides antibody on Pregnancy outcomes

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion Criteria: First trimester pregnancy Exclusion criteria: Thyroid diseases, TSH less than 0.2 or > 4 ng/ml, recurrent abortion (3 consecutive abortions)

#### Age

From **15 years** old to **45 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **32**

## 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

Kurdistan University of Medical Sciences

##### Street address

Kurdistan University of medical sciences, Pasdaran Ave

##### City

Sanandaj

##### Postal code

#### Approval date

2010-02-03, 1388/11/14

#### Ethics committee reference number

10576پ14پ

## Health conditions studied

### 1

#### Description of health condition studied

thyroid peroxides antibody

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

premature delivery

#### Timepoint

at the end of pregnancy

#### Method of measurement

observation

## Secondary outcomes

### 1

#### Description

premature rupture of membrane

#### Timepoint

at the end of pregnancy

#### Method of measurement

observation

### 2

#### Description

delivery type

#### Timepoint

at the end of pregnancy

#### Method of measurement

observation

### 3

#### Description

newborn's Apgar score

#### Timepoint

at end of pregnancy

#### Method of measurement

observation

### 4

#### Description

newborn's weight

#### Timepoint

at the end of pregnancy

#### Method of measurement

observation

## Intervention groups

### 1

#### Description

Control group: No treatment

#### Category

N/A

### 2

#### Description

Intervention group: a daily dose of 50 microgram levothyroxine during pregnancy

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Besat Hospital

##### Full name of responsible person

Fariba Seyedoshohadaei

##### Street address

Besat Hospital, Keshavarz Ave

##### City

Sanandaj

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Kurdistan University of Medical Sciences

**Full name of responsible person**

Ataollah Heidari

**Street address**

Kurdistan University of Medical Sciences, Pasdaran Ave

**City**

Sanandaj

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kurdistan 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**

Kurdistan University of Medical Sciences

**Full name of responsible person**

Fariba Seyedoshohadaei

**Position**

Associate Prof.

**Other areas of specialty/work**

**Street address**

Besat Hospital

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**Fax**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kurdistan University of Medical Sciences

**Full name of responsible person**

Shahla Nouroozi

**Position**

Resident

**Other areas of specialty/work**

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Besat Hospital, Keshavarz Ave

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## 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*