

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 Seyedshohadaei

Position

Associate Prof.

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Shahla Nouroozi

Position

Resident

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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