Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Oct 2026

Assessment of the effect of Levothyroxine on the infant development status in pregnant women with autoimmune non overt thyroid disease

Protocol summary

Summary

This study will be conducted in two stages: In the first stage, 1600 pregnant women were evaluated in the first trimester of pregnancy and a questionnaire including demographic characteristics, medical and midwifery history were completed. Also, their thyroid is examined. Blood samples were taken from sera for TSH, T4, T-uptake and Thyroid peroxidase antibodies (TPOAb) tests. According to the results of the laboratory test, TPOAb positive women (≥50 IU per mL) with TSH >10 µIU per mL in the first 20 weeks of pregnancy is identified as autoimmune non overt thyroid disease and entering the second stage of the study. In the second stage, women with autoimmune non overt thyroid disease with a single pregnancy are randomly divided into two groups of intervention and control. The first group is the intervention group that is treated with levothyroxine and the second group does not receive any intervention. Pregnant women are followed to delivery. After delivery, the developmental status of children is evaluated using Ages and Stages Questionnaire (ASQ) completed by parents for each of the five areas of communication, gross motor, Fine motions, problem solving and personal, social skills. The researcher did not know the sample group when collecting information and completing the questionnaire. The Children developmental status in the two intervention and control groups is examined and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017090414849N6**
Registration date: **2017-10-14, 1396/07/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-10-14, 1396/07/22

Registrant information

Name
Sima Nazarpour
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 6656 0340
Email address
simanazarpour@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of Levothyroxine on the infant development status in pregnant women with autoimmune non overt thyroid disease

Public title

The effect of Levothyroxine on the infant development status in pregnant women with autoimmune non overt thyroid disease

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women during the first 20 weeks of pregnancy. Exclusion criteria: multiple pregnancy.

Age

From **15 years** old to **46 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **1600**

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

Ethics Committee Research Institute for Endocrine Sciences and Metabolism of Shahid Beheshti Univers

Street address

No. 24, Arabi street, Yemen street, Velenjak, Tehran, Iran

City

Tehran

Postal code

1985717413

Approval date

2017-03-01, 1395/12/11

Ethics committee reference number

IR.SBMU.ENDOCRINE.REC.1395.299

Health conditions studied

1

Description of health condition studied

Thyroid disorders

ICD-10 code

E07.9

ICD-10 code description

Disorder of thyroid, unspecified

Primary outcomes

1

Description

Communication developmental status

Timepoint

Since 4 months after birth

Method of measurement

Ages and Stages Questionnaire (ASQ)

2

Description

Gross motor developmental status

Timepoint

Since 4 months after birth

Method of measurement

Ages and Stages Questionnaire (ASQ)

3

Description

Fine motor developmental status

Timepoint

Since 4 months after birth

Method of measurement

Ages and Stages Questionnaire (ASQ)

4

Description

Problem solving developmental status

Timepoint

Since 4 months after birth

Method of measurement

Ages and Stages Questionnaire (ASQ)

5

Description

Personal, social developmental status

Timepoint

Since 4 months after birth

Method of measurement

Ages and Stages Questionnaire (ASQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group will treat with Levoxine (Levothyroxine sodium). These patients will receive a daily dose of 0.5 µg per kg if they have TSH <1.0 µIU per mL, 0.75 µg per kg for TSH between 1.0 and 2.0 µIU per mL, and a 1 µg per kg for TSH >2.0 µIU per mL or a TPOAb titer exceeding 1500 IU per mL. Dosages will maintain throughout pregnancy until delivery. In this

study are used from Levothyroxine sodium 0.1 mg manufactured by Iran Hormone.

Category

Treatment - Drugs

2

Description

There is no intervention for the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Centers under coverage of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Grant for research projects section

Street address

Arabi street, Yaman Avenue, Shahid Chamran Highway, Tehran. Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Research Institute for Endocrine Sciences

Full name of responsible person

Sima Nazarpour

Position

PhD, Researcher

Other areas of specialty/work

Street address

No. 24, Arabi street, Yemen street, Velenjak, Tehran, Iran

City

Tehran

Postal code

1985717413

Phone

+98 21 2243 2500

Fax

Email

snazarpour@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Research Institute for Endocrine Sciences

Full name of responsible person

Fahimeh Ramezani Tehrani

Position

Gynecologist

Other areas of specialty/work

Street address

No. 24, Arabi street, Yemen street, Velenjak, Tehran, Iran

City

Tehran

Postal code

1985717413

Phone

+98 21 2243 2500

Fax

Email

fah.tehrani@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Research Institute for Endocrine Sciences

Full name of responsible person

Sima Nazarpour

Position

PhD, Researcher

Other areas of specialty/work

Street address

No. 24, Arabi street, Yemen street, Velenjak, Tehran, Iran

City

Tehran

Postal code

1985717413

Phone
+98 21 2243 2500
Fax
Email
snazarpour@gmail.com
Web page address

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