

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Assessment of the effect of Levothyroxine on pregnancy outcome in comparison with placebo in pregnant women with subclinical hypothyroidism and positive thyroid peroxidase antibody

Protocol summary

Summary

This study will be conducted to determine the effectiveness of the effect of Levothyroxine on pregnancy outcome of pregnant women with subclinical hypothyroidism and positive thyroid peroxidase antibody (TPOAb) of two parts: in the first stage thyroid hormones are tested in 1600 pregnant women in the first 20 weeks of pregnancy and Pregnant women with subclinical hypothyroidism and positive TPOAb are identified. Three times urine during a week are also sampled for iodine measurement. Women with TPOAb positive (more than 50 kIU/l) and TSH between 2.5 and 10 mIU/ liter in the first 20 weeks of pregnancy, will enter into the second phase of the study. In the second stage of study, pregnant women with subclinical hypothyroidism and positive TPOAb are divided simple randomly (based on the odd or even sample code) into two groups. The first group, intervention group, is treated with levothyroxine. The second group, control group, received placebo. In the second and third trimester, maternal serum samples are taken. Both groups are followed up until delivery and abnormal cases are recorded. In the second and third trimester, women's serum samples are evaluated for TSH, T4 and T3uptake and newborns' serum samples are collected for TSH analysis. The intervention groups is compared with control group according to pregnancy outcome including: abortion, preterm labor, low birth weight, intrauterine growth restriction, premature rupture of membrane, third trimester hemorrhage and newborns' thyroid hormone levels at birth.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112014849N2**
Registration date: **2014-01-06, 1392/10/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-06, 1392/10/16

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

2013-10-23, 1392/08/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of Levothyroxine on pregnancy outcome in comparison with placebo in pregnant women with subclinical hypothyroidism and positive thyroid

Public title

The effect of Levothyroxine on pregnancy outcome of pregnant women with subclinical hypothyroidism and positive thyroid peroxidase antibody

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women during the first 20 weeks of pregnancy.should not have contraindications for taking levothyroxine contraindication of Levothyroxine include: patients with severe cardiovascular diseases such as coronary heart failure, history of myocardial infarction, uncontrolled hypertension

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In this clinical trial no subject knows whether she is receiving particular treatments (levothyroxine) or lack of treatment (placebo), but the administrator does have that information.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical

Street address

Velenjak St. , Shahid Chamran Highway, Tehran, Iran

City

Tehran

Postal code

Approval date

2013-10-15, 1392/07/23

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Abortion

ICD-10 code

O03

ICD-10 code description

Spontaneous abortion

2

Description of health condition studied

Preterm labor

ICD-10 code

O60

ICD-10 code description

Preterm labour and delivery

3

Description of health condition studied

Low birth weight

ICD-10 code

P07

ICD-10 code description

Disorders related to short gestation and low birth weight, not elsewhere classified

4

Description of health condition studied

Intra uterine growth restriction

ICD-10 code

P05

ICD-10 code description

Slow fetal growth and fetal malnutrition

5

Description of health condition studied

Premature rupture of membranes

ICD-10 code

O42

ICD-10 code description

Premature rupture of membranes

6

Description of health condition studied

Third trimester hemorrhage

ICD-10 code

O44 , O45

ICD-10 code description

Placenta previa, Premature separation of placenta [abruptio placentae]

Primary outcomes

1

Description

Abortion

Timepoint

Up to 20 weeks of pregnancy (In cases that intervention begins in first trimester)

Method of measurement

Checklist

2

Description

Preterm labor

Timepoint

20 to 37 weeks of pregnancy (within 1 to 6 months after intervention)

Method of measurement

Checklist

3

Description

Low birth weight

Timepoint

After birth (5 to 7 months after intervention)

Method of measurement

Checklist

4

Description

Intra uterine growth restriction

Timepoint

5 to 7 months after intervention

Method of measurement

Checklist

5

Description

Premature rupture of membranes (PROM)

Timepoint

5 to 7 months after intervention

Method of measurement

Checklist

6

Description

Third trimester hemorrhage

Timepoint

Third trimester (2 to 5 months after intervention)

Method of measurement

Checklist

7

Description

TSH level of newborn at birth (day 3 to 5 births)

Timepoint

3 to 5 days after birth (5 to 7 months after intervention)

Method of measurement

Immunoradiometric assay (IRMA)

Secondary outcomes

1

Description

Thyroid hormones (T4, T3 uptake, TSH) in second and third trimester

Timepoint

20th and 30th week of pregnancy

Method of measurement

T4: Radioimmuno assay (RIA), TSH: Immunoradiometric assay (IRMA), T3uptake: ELISA

2

Description

Blood pressure

Timepoint

After the intervention, during routine care in pregnancy (16 to 20 weeks, 26 to 30 weeks, 31 to 34 weeks, 35 to 37 weeks, 38 weeks, 39 weeks, 40 or 41 weeks of gestation) and during labor

Method of measurement

Blood pressure measuring devices

3

Description

Edema

Timepoint

After the intervention, during routine care in pregnancy (16 to 20 weeks, 26 to 30 weeks, 31 to 34 weeks, 35 to 37 weeks, 38 weeks, 39 weeks, 40 or 41 weeks of gestation)

Method of measurement

Checklist

4

Description

Fetal heart rate (FHR)

Timepoint

After the intervention, during routine care in pregnancy (16 to 20 weeks, 26 to 30 weeks, 31 to 34 weeks, 35 to 37 weeks, 38 weeks, 39 weeks, 40 or 41 weeks of gestation) and during labor

Method of measurement

Pinard Stethoscope

5

Description

Headache

Timepoint

After the intervention, during routine care in pregnancy (16 to 20 weeks, 26 to 30 weeks, 31 to 34 weeks, 35 to 37 weeks, 38 weeks, 39 weeks, 40 or 41 weeks of gestation)

Method of measurement

Checklist

6

Description

Vaginal bleeding

Timepoint

After the intervention, during routine care in pregnancy (16 to 20 weeks, 26 to 30 weeks, 31 to 34 weeks, 35 to 37 weeks, 38 weeks, 39 weeks, 40 or 41 weeks of gestation) and during labor

Method of measurement

Checklist

7

Description

Uterine contractions

Timepoint

After the intervention, during routine care in pregnancy (16 to 20 weeks, 26 to 30 weeks, 31 to 34 weeks, 35 to 37 weeks, 38 weeks, 39 weeks, 40 or 41 weeks of gestation)

Method of measurement

Checklist

8

Description

Type of delivery

Timepoint

Delivery (5 to 7 months after intervention)

Method of measurement

Checklist

9

Description

Postpartum atonia

Timepoint

Postpartum (5 to 7 months after intervention)

Method of measurement

Checklist

10

Description

Postpartum hemorrhage

Timepoint

Postpartum (5 to 7 months after intervention)

Method of measurement

Checklist

11

Description

Newborn Apgar

Timepoint

After birth (5 to 7 months after intervention)

Method of measurement

Apgar scoring

12

Description

Hospitalization in neonatal intensive care unit (NICU)

Timepoint

After birth (5 to 7 months after intervention)

Method of measurement

Checklist

13

Description

Newborn convulsion

Timepoint

After birth (5 to 7 months after intervention)

Method of measurement

Checklist

14

Description

Newborn icterus

Timepoint

After birth (5 to 7 months after intervention)

Method of measurement

Checklist

Intervention groups

1

Description

Intervention group will treat with Levoxine (Levothyroxine sodium). These patients will receive 1 mg per kg of body weight daily levothyroxine. 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

Will take placebo.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Varamin, Pishva and Qarchak

Full name of responsible person

Sima Nazarpour

Street address

Varamin, Pishva , Qarchak

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi (Vice chancellor for research, Shahid Beheshti University of Medical Sciences)

Street address

Velenjak Street , Shahid Chamran Highway, Tehran.

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

Shahid Beheshti University of Medical Sciences,
Midwifery and Nursing department

Full name of responsible person

Sima Nazarpour

Position

PhD student in the field of Reproductive Health

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Niayesh st., Vali Asr Ave., Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 8865 5366

Fax

Email

nazarpoursima@yahoo.comsimanazarpour@sbmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Research Institute for Endocrine Sciences, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fahimeh Ramezani Tehrani

Position

Gynecologist

Other areas of specialty/work

Street address

Velenjak St. , Shahid Chamran Highway, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 2243 2500

Fax

Email

fah.tehrani@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
Nursing and Midwifery department

Full name of responsible person

Sima Nazarpour

Position

PhD student in the field of Reproductive Health

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Niayesh st., Vali Asr Ave., Tehran, Iran

City

Tehran

Postal code

Phone

00

Fax

Email

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