Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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

peroxidase antibody

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
32ECRIES92/07/23

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 to5 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

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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Position
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Other areas of specialty/work

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Person responsible for updating data

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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