Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

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

Protocol summary

Study aim

Assessment of the effect of Levothyroxine on pregnancy outcome in pregnant women with subclinical hypothyroidism and negative thyroid peroxidase antibody.

Design

]n the first stage thyroid hormones are tested in 160 pregnant women in the first 20 weeks of pregnancy and pregnant women with subclinical hypothyroidism and TPOAb negative are identified. The urines of these women are also sampled for iodine measurement. The second stage is a parallel group randomised clinical trial with control group, community based and one blinded study. it is phase two of clinical trials. In the second stage of study, pregnant women with subclinical hypothyroidism and negative TPOAb are divided simple randomly into two groups using permuted block randomization . The first group, intervention group, is treated with levothyroxine. The second group, as control group did not receive intervention.In the second and third trimester, maternal serum samples are taken. Both groups are followed up until delivery.

Settings and conduct

Data collection from pregnant women is done in prenatal care clinics. A comprehensive questionnaire including demographics, reproductive, medical and prenatal history was completed. Thyroid tests are performed to diagnose pregnant women with subclinical hypothyroidism TPOAb negative.

Participants/Inclusion and exclusion criteria

pregnant women during the first 20 weeks of pregnancy should not have contraindications for taking levothyroxine contraindication of

Intervention groups

The intervention group, is treated with levothyroxine. The control group does not receive intervention.

Main outcome variables

Abortion, preterm labor, low birth weight, intrauterine growth restriction, premature rupture of membranes and third trimester hemorrhage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121214849N3**
Registration date: **2014-01-06, 1392/10/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-17, 1397/04/26**
Update count: **1**

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 pregnant women with subclinical hypothyroidism and negative thyroid peroxidase antibody

Public title
The effect of Levothyroxine on pregnancy outcome of pregnant women with subclinical hypothyroidism and negative thyroid peroxidase antibody
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: pregnant women during the first 20 weeks of pregnancy.
Exclusion criteria:
contraindication of Levothyroxine use 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

- Investigator
- Outcome assessor

Sample size
Target sample size: **1600**
Randomization (investigator's opinion)
Randomized
Randomization description
Study subjects are randomly divided into two groups using permuted block randomization to achieve balance across treatment groups. The number of subjects per block will be four.
Blinding (investigator's opinion)
Single blinded
Blinding description
A sealed opaque envelope will be assigned to each subject, only the midwife treating the women, who will not participate in any subsequent phase of the study, knows in which group each patient is.
Placebo
Not used
Assignment
Parallel
Other design features

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
Province
Tehran
Postal code
1985717413
Approval date
2013-10-15, 1392/07/23
Ethics committee reference number
33ECRIES92/07/23

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 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

The control group does not receive intervention.

Category
N/A

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
Varamin
Province
Tehran
Postal code
1985717413
Phone
+98 21 2243 2500
Email
snazarpour@gmail.com

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
Province
Tehran
Postal code
1985717413
Phone
+98 21 2243 2500
Email
fah.tehrani@gmail.com
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
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sima Nazarpour
Position
Assistant Professor, PhD of Reproductive Health
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
School of Nursing and Midwifery, Niayesh st., Vali Asr Ave., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 8865 5366
Fax
Email
simanazarpour@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
Latest degree
Specialist
Other areas of specialty/work
Street address
Velenjak St. , Shahid Chamran Highway, Tehran, Iran
City
Tehran
Province
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
Shahid Beheshti University of Medical Sciences, Nursing and Midwifery department

Full name of responsible person
Sima Nazarpour

Position
Assistant Professor,PhD of Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work

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

City
Tehran

Province
Tehran

Postal code
1985717413

Phone
00

Fax

Email
nazarpoursima@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
-

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
-

When the data will become available and for how long
-

To whom data/document is available
-

Under which criteria data/document could be used
-

From where data/document is obtainable
-

What processes are involved for a request to access data/document
-

Comments
-