

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Assessment of the effect of Levothyroxine on pregnancy outcome in comparison with placebo in pregnant women with isolated hypothyroxinemia

#### Protocol summary

##### Summary

This study will be conducted to determine the effectiveness of the effect of Levothyroxine on pregnancy outcome of pregnant women with isolated hypothyroxinemia 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 in pregnant women with isolated hypothyroxinemia are identified. Three times urine during a week are also sampled for iodine measurement. Women with normal TSH less than 2.5 mIU/ liter) and FTI less than 1 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 in pregnant women with isolated hypothyroxinemia 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: **IRCT2013121714849N4**  
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 isolated hypothyroxinemia

## Public title

The effect of intervention by Levothyroxine on pregnancy outcome of pregnant women with isolated hypothyroxinemia

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: pregnant women during the first 20 weeks of pregnancy. should not have contraindications for taking levothyroxine. Contraindications 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: **60**

## 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 Shahid Beheshti University of Medical Sciences, Research Institute for Endocrin

##### 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

33ECRIES92/07/23

## Health conditions studied

### 1

#### Description of health condition studied

Preterm labor

#### ICD-10 code

O60

#### ICD-10 code description

Preterm labour and delivery

### 2

#### Description of health condition studied

Abortion

#### ICD-10 code

O03

#### ICD-10 code description

Spontaneous abortion

### 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 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 LT4: these patients will receive a dose of 0.5 microgram/kg.d if they have TSH less than 1.0 mIU/liter, 0.75 microgram/kg.d for TSH between 1.0 and 2.0 mIU/liter, and 1 microgram/kg.d for TSH higher than 2.0 mIU/liter. Dosages will maintain throughout gestation.

#### **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**

Varamin

## **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**

simanazarpour@sbmu.ac.ir; nazarpoursima@yahoo

**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*