Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

The effect of using two subclinical hypothyroid treatment approaches during pregnancy on the adverse outcomes of pregnancy

Protocol summary

Study aim
Prevention of Over-Treatment of Pregnant Women
Design
A clinical trial with community-based control and practice-oriented, double blind, randomized clinical trials
Settings and conduct
The study population was selected from pregnant women with TSH levels between 2.5 to 9.3 in the first trimester and 3 to 1.4 in the second and third trimester of pregnancy referred to Endocrine clinic of Valiasr Hospital in Zanjan. The method of blindness is done in such a way that the patient returns to the therapist after referral to the center expert and the appointment of A or B group.
Participants/Inclusion and exclusion criteria
Pregnant women with TSH levels ranging from 2.5 to 3.9 in the first trimester; and between 3 to 4.1 in the second and third trimesters; and have no history of spontaneous abortion or previous thyroid disease
Intervention groups
The first group is an intervention group that is treated with levothyroxine tablets at a dose of at least 50 micrograms per day, and the second group, the "control group", does not receive a drug and is only followed up.
Main outcome variables
pregnancy loss

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180314039091N1**
Registration date: **2018-05-21, 1397/02/31**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-21, 1397/02/31**
Update count: **0**
Registration date
2018-05-21, 1397/02/31

Registrant information
Name
Farahnaz Mir
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-04-09, 1397/01/20
Expected recruitment end date
2018-08-22, 1397/05/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of using two subclinical hypothyroid treatment approaches during pregnancy on the adverse outcomes of pregnancy

Public title
Effect of TSH Level on adverse Outcome of Pregnancy in Subclinical Hypothyroidism
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women with TSH levels ranging from 2.5 to 9.3 in the first trimester of pregnancy and TSH levels

between 3 to 1.4 in the second and third trimesters Their free T4 levels are within the normal range Thyroid size is normal in the examination, and the nodule or mass is not touched Pregnant women who do not have a history of thyroid disease Do not have a history of Pregnancy Loss. There is no history of thyroid surgery

Exclusion criteria:

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

A specialist at the Metabolic Disease Research Center, participants randomly divided into two group A and B

Blinding (investigator's opinion)

Double blinded

Blinding description

A specialist at the Metabolic Disease Research Center, participants randomly divided into two groups of control and intervention.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zanjan University of Medical Sciences Ethics Committee

Street address

Metabolic Diseases Research Center, Vali-asr Hospital, Zanjan, Iran

City

Zanjan

Province

Zanjan

Postal code

کدپستی 4515777978

Approval date

2017-12-12, 1396/09/21

Ethics committee reference number

ZUMS.REC.1396.225

Health conditions studied

1

Description of health condition studied

Subclinical hypothyroidism

ICD-10 code

E02

ICD-10 code description

Subclinical iodine-deficiency hypothyroidism

Primary outcomes

1

Description

pregnancy Loss

Timepoint

Until 20 weeks for abortion and until delivery for IUFD and Fetal Loss

Method of measurement

check list

2

Description

Eclampsia

Timepoint

During pregnancy care

Method of measurement

Sphygmomanometer

3

Description

neonatal death

Timepoint

Delivery

Method of measurement

check list

4

Description

11/5000Showing translation for آپگار پایینTranslate instead آپکار پائینApgar lower

Timepoint

Delivery

Method of measurement

Apgar score

5

Description

Preterm Labour and Delivery

Timepoint

From 20 to 37 weeks of pregnancy

Method of measurement

Check list

6

Description

Intra Uterim Growth Restrection

Timepoint

During pregnancy

Method of measurement

Ultrasound

7

Description

Premature rupture of membranes

Timepoint

Third Trimsters Pregnancy

Method of measurement

Chek list

8

Description

Placenta previa - premature separation of pelacenta - abruptio placenta

Timepoint

Pregnancy

Method of measurement

Chek list

Secondary outcomes

1

Description

Thyroid hormones(FT4 - T4 - TSH - TOP Ab)

Timepoint

Until the 20th of every month and then at week 32 to 36

Method of measurement

T4 and TSH (ECL method) FT4 and TPO Ab (ICMA method)

Intervention groups

1

Description

Intervention group: Levothyroxine tablets are treated with at least 50 micrograms per day and continue throughout pregnancy until delivery. Patient pills are made by Iranian hormones company.

Category

Treatment - Drugs

2

Description

Control group: They do not receive any drug and they are only under follow up.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology Clinic of Valiasr Hospital in Zanjan

Full name of responsible person

Farahnaz Mir

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Vali-asr Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr Ali reza Shoghli

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zanjan 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
Zanjan University of Medical Sciences
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Farahnaz Mir
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Fellow of Endocrin
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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
No more information
Study Protocol
No - There is not 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
No - There is not 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