

# Miscarriage and Levothyroxine treatment in euthyroid spontaneously pregnant women with thyroid AntiBodies

<b>Submission date</b> 27/04/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/05/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/05/2021	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The body produces antibodies as part of a normal immune response to foreign invaders, like viruses and bacteria. Thyroid antibodies are antibodies targeted against the thyroid gland. Research suggests that women with thyroid antibodies experience an higher rate of miscarriage when compared to women without thyroid antibodies. The aim of this study is to find out whether early treatment with Levothyroxine increases the proportion of women who attain a live birth beyond 34 completed weeks of gestation by at least 50%.

### Who can participate?

Women aged 18-40 in the first trimester of pregnancy with thyroid antibodies.

### What does the study involve?

Patients are randomly assigned to one of two groups. One group is treated with Levothyroxine and the other group is left untreated.

### What are the possible benefits and risks of participating?

There is no additional risk for untreated subjects; potential benefit for treated subjects.

### Where is the study run from?

Vito Fazzi Hospital (Italy).

### When is the study starting and how long is it expected to run for?

The study started in January 2011 and will run until December 2014.

### Who is funding the study?

Vito Fazzi Hospital (Italy).

### Who is the main contact?

Dr Roberto Negro  
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# Contact information

## Type(s)

Scientific

## Contact name

Dr Roberto Negro

## Contact details

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# Additional identifiers

## Protocol serial number

N/A

# Study information

## Scientific Title

Miscarriage and Levothyroxine treatment in euthyroid spontaneously pregnant women with thyroid Antibodies: an interventional randomised single-centre trial

## Acronym

MiLAB

## Study objectives

We hypothesized that treatment with Levothyroxine in euthyroid spontaneously pregnant patients within the first trimester of pregnancy may reduce the rate of miscarriage.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Institutional Review Board, 11/11/2010

## Study design

Interventional randomised single-centre trial

## Primary study design

Interventional

## Study type(s)

Prevention

## Health condition(s) or problem(s) studied

Chronic autoimmune thyroiditis in pregnancy

## Interventions

The study involves first trimester pregnant women with positive TPOAb and/or TgAb and TSH <2.5 mIU/L. Patients are randomly assigned to two groups, one treated with Levothyroxine, and one left untreated.

Treated arm: patients with TSH 0.5-1.5mIU/L take 0.5 mcg/kg weight of Levothyroxine daily; patients with TSH 1.5-2.5 mIU/L take 1 mcg/Kg weight of Levothyroxine daily.

Untreated arm: patients with first trimester TSH 0.5-2.5mIU/L left untreated. TSH checked once in the second and once in the third trimester; if TSH >3.0mIU/L, patients are treated with Levothyroxine 1 mcg/kg pre-pregnancy weight daily.

## Intervention Type

Drug

## Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

Levothyroxine

## Primary outcome(s)

Number of miscarriages, defined as fetal death within 20 weeks of gestation. Time point is 20 weeks of gestation

## Key secondary outcome(s)

Number of preterm births, defined as birth before 37 complete weeks of gestation. Time point is end of pregnancy

## Completion date

31/12/2014

## Eligibility

### Key inclusion criteria

1. Women in the first trimester of pregnancy
2. Age 18-40
3. TSH: 0.5-2.5 mIU/L
4. FT4 in the normal range
5. Thyroid Peroxidase Antibody (TPO) positive
6. Willing and able to give informed consent

### Participant type(s)

Patient

### Healthy volunteers allowed

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

40 years

**Sex**

Female

**Total final enrolment**

590

**Key exclusion criteria**

1. Current or past treatment for thyroid disease
2. Contraindication to levothyroxine treatment
3. Drugs interfering with thyroid function

**Date of first enrolment**

01/01/2011

**Date of final enrolment**

31/12/2014

**Locations****Countries of recruitment**

Italy

**Study participating centre**

Piazza F. Muratore, 1

Lecce

Italy

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**Sponsor information****Organisation**

Vito Fazzi Hospital (Italy)

**ROR**

<https://ror.org/04fvmv716>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Vito Fazzi Hospital (Italy)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		01/10/2016	10/05/2021	Yes	No