

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

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| Submission date 27/04/2014 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 21/05/2014 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 10/05/2021 | Condition category 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? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| Results article | | 01/10/2016 | 10/05/2021 | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |