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

Submission date
27/04/2014

Recruitment status
No longer recruiting

Registration date
21/05/2014

Overall study status
Completed

Last Edited
10/05/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

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

Overall study start date
01/01/2011

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
175 patients for each arm (350 in total)

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
73100

Sponsor information

Organisation
Vito Fazzi Hospital (Italy)

Sponsor details
Piazza F. Muratore, 1
Lecce
Italy
73100

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04fvmv716

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Vito Fazzi Hospital (Italy)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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