The Brabant Study: a prospective cohort study among pregnant women

Published: 01-02-2018
Last updated: 12-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thyroid gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON52874

Source
ToetsingOnline

Brief title
The Brabant Study

Condition

- Thyroid gland disorders
- Pregnancy, labour, delivery and postpartum conditions
- Mood disorders and disturbances NEC

Synonym
thyroid dysfunction during pregnancy

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: depression, obstetric complications, pregnancy, thyroid function

Outcome measures

Primary outcome

Thyroid hormone levels (TSH and fT4) and TPO-Ab and hCG assessed at 12, 20 and 28 weeks.

Secondary outcome

Pregnancy complications (e.g. pre-eclampsia, pre-term birth, SGA), mode of delivery (spontaneous versus instrumental delivery) and depressive symptoms related to thyroid trajectories and/or poor obstetric outcome.

Study description

Background summary

Adequate maternal thyroid function (thyrotropin (TSH) and free thyroid hormone (fT4)) is extremely important during pregnancy for the developing foetus and is subject to substantial physiological changes throughout gestation.
Cross-sectional measurements of TSH and fT4 have been related in many studies to various obstetric outcomes including gestational diabetes, pre-eclampsia and abnormal foetal position. Only few studies have observed an association between outcomes and both TSH and fT4, whereas most others have reported a relationship either with TSH but not fT4, or vice versa. Similarly, there are numerous studies reporting a possible relation between thyroid dysfunction and depression / depressive symptoms at a cross-sectional level and most of the time for fT4 or TSH separately. LCA analyses recently showed new insights of physiological thyroid function changes during pregnancy. However, the power of these first LCA gestational thyroid function analyses was low and hCG assessments (an important pregnancy hormone with major impact on thyroid function as well) were not performed. Therefore, larger samples are needed in order to compare the incidence of these complications between different trajectories and TSH / fT4 should be adjusted for hCG. LCA has also been used to report trajectories of depressive symptoms during pregnancy.

Study objective

The main objective of the Brabant Study (BS) is to investigate possible different trajectories of thyroid function during pregnancy taking hCG hormone into account. Moreover, we aim to investigate whether pregnancy complications (e.g. pre-eclampsia, pre-term birth) and mode of delivery (spontaneous versus instrumental delivery) are related to these trajectories. Also, we will investigate whether trajectories of thyroid dysfunction are related to depressive symptoms during pregnancy. Finally, the role of partner relationship on pregnancy distress will be investigated and the possible role of distress on absenteeism.

Study design

The current study is a longitudinal, prospective cohort study among 4000 pregnant women. They will be recruited among community midwife practices in South-East Brabant in the Netherlands (Tilburg, Eindhoven and Den Bosch).

Study burden and risks

Participants will receive three questionnaires (15-20 minutes to complete) and will provide three blood samples during pregnancy. The blood samples at 12 and 28 weeks are part of regular routine obstetric care, only the collection of an additional tube of blood is needed. The blood sample at 20 weeks is an additional burden for participants in this study. Moreover, the women will receive a (optional) home visit or telephone interview, at 8-10 weeks postpartum (lasting 1 hour).
No risks have been reported for the burden for the participants into the current study: an additional blood assessment by vena-punction and completing of questionnaires by the women.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

- Pregnant women (18+ y) who have their first antenatal visit < 14 weeks
- Dutch or English-speaking or understanding Dutch or English

Exclusion criteria

- Multiple pregnancy
- Known endocrine disorder before pregnancy
- Use of thyroid medication
- Severe psychiatric disease (e.g. schizophrenia, borderline, bipolar disorder or depression with known suicidal ideation)
- HIV
- Drug or alcohol addiction problems
- Any other disease resulting in treatment with drugs that are potentially adverse for the foetus and need careful follow-up during pregnancy (e.g. Type 2 Diabetes with use of insulin, Rheumatoid Arthritis with use of prednison or methotrexate, Multiple Sclerosis or Crohn's disease).
- No access to internet

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-05-2018
Enrollment:	4000
Type:	Actual

Ethics review

Approved WMO Date:	01-02-2018
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	21-01-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	16-04-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	26-08-2020
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	02-02-2022
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL64091.015.17