HAPPY-follow: Longitudinal follow-up of mothers and children of the HAPPY study (Holistic Approach to Pregnancy and first Postpartum Year)

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The primary objectives :Are children of mothers with sub-optimal thyroid function and/or sub-clinical hypothyroidism and/or hypothyroxinemia during early pregnancy at risk for developmental delay at the age of two and does this possible delay…

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

Summary

ID

NL-OMON42645

Source
ToetsingOnline

Brief title
HAPPY-follow

Condition

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

Synonym
developmental delay

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Stichting de Weijerhorst

Intervention

Keyword: children, depression, Development, thyroid

Outcome measures

Primary outcome

We will compare developmental scores of children of mothers with and without maternal thyroid dysfunction during gestation and of mothers with and of mothers with and without depression during pregnancy and the post-partum. Moreover, we will compare ultrasound data at 20 weeks gestation (cerebellum size, ventricle size and bi-parietal diameter) in the thyroid group and the healthy controls, possibly correlating thyroid function to CNS parameters.

Secondary outcome

N/A

Study description

Background summary

During the HAPPY study (Holistic Approach to Pregnancy and first Postpartum Year) 2250 pregnant women have been included in a longitudinal study in 2013-2014. During pregnancy maternal thyroid function and maternal mood were monitored. Maternal thyroid function is essential for the development of the central nervous system of the fetus which until 20 weeks does not produce thyroid hormone. Furthermore, a standardized 20 weeks ultrasound has been conducted during which several parameters of the central nervous system (CNS) have been collected: cerebellum size, ventricle size and bi-parietal diameter. At 12, 24 and 32 weeks symptoms of depression were assessed. With the data we collected, we were able to construct a vulnerability profile for women who are

vulnerable to (recurrent) depression.

Study objective

The primary objectives :
Are children of mothers with sub-optimal thyroid function and/or sub-clinical hypothyroidism and/or hypothyroxinemia during early pregnancy at risk for developmental delay at the age of two and does this possible delay persist at preschool age (3.5 years of age)?
Are children of mothers with recurrent depression during pregnancy at risk for developmental delay at the age of two and does this possible delay persist at preschool age (3.5 years of age)?

The secondary objectives :
Is there any correlation between developmental delay of children of mothers with sub-optimal thyroid function during gestation and CNS parameters (cerebellum size, ventricle size, bi-parietal diameter), assessed at 20 weeks gestation on ultrasound?
Is early recognition of developmental problems in children followed by referral to usual care associated with better developmental scores at further follow-up?

Study design

Observational study with two assessments.

Study burden and risks

The Bayley-III-NL is a playful test that is usually enjoyed by children. The benefit for the child of doing this test is that developmental delays can be detected at an early age and that the child and parents can be supported in coping with and/or overcoming the developmental delay.
There is no risk associated with the Bayley-III-NL test.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, mothers who participated in the HAPPY study and their children that were born during the HAPPY study must meet the following criteria:
• 200 mothers with recurrent depressive symptoms during pregnancy and their (200) children. Within HAPPY there were 3 assessments of depression during pregnancy, and five during postpartum. Recurrent depression is defined as an EDS score above cut-off at three consecutive assessment during pregnancy and/or at least three times an EDS above the cut-off during the 12 months postpartum follow-up.
• 150 mothers with sub-optimal thyroid function (elevated TPO-Ab titres; 8.8% of 1353 women = 119) and /or sub-clinical hypothyroidism (TSH > 90th percentile = 135 women) and / or hypothyroxinemia. (FT4 < 10th percentile = 135 women) and their children (150). Because of substantial overlap between elevated TPO-Ab titres and high TSH women, a conservative estimation result in 150 women (and their children) who meet one or more of these criteria. If the sample of women who meet these criteria is higher than 150, SPSS will give a random selected sample.
• A control group of 200 mothers who did not have elevated depression scores during pregnancy, with thyroid function within trimester specific reference limits (between 25th and 75th percentile), not suffering from chronic conditions, and their children.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation

in this study:
- Hospitalization in a psychiatric hospital in the previous 12 months
- A known serious psychiatric disease diagnosis (bi-polar disorder, psychotic depression, personality disorder) at the time of the home visit
- Severe depression with suicidal ideation during home visit

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-10-2015
Enrollment:	1100
Type:	Actual

Ethics review

Approved WMO

Date:	06-10-2015
Application type:	First submission
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	NL54558.015.15

Study results

Date completed:	31-12-2019
Actual enrolment:	511