Pregnancy and Infant Development Study

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON32537

Source
ToetsingOnline

Brief title
PRIDE Study

Condition

- Other condition
- Congenital and hereditary disorders NEC
- Pregnancy, labour, delivery and postpartum conditions

Synonym
pregnancy / development

Health condition

pre- en postnatele ontwikkeling

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,NWO Toptalent subsidie

Intervention

Keyword: child health, development, maternal health, pregnancy

Outcome measures

Primary outcome

The main focus will be on the health status of the (pregnant) woman and her (unborn) child. Therefore, multiple primary outcome parameters have been defined, including pregnancy complications (specifically hypertension and diabetes), spontaneous abortions, stillbirths, birth defects, gestational age, birth weight, and indicators for functional development of the infant.

Secondary outcome

Not applicable.

Study description

Background summary

The PRIDE Study will be conducted to gain more knowledge about the causes of maternal and infant disorders and diseases that originate in pregnancy, including gestational hypertension, spontaneous abortions, and major birth defects. Knowledge about risk factors for these disorders and diseases is limited, but an influence of both genetic and environmental factors are described in the medical scientific literature. For example, for 60-70% of birth defects the cause is unknown and knowledge about the aetiology of pregnancy-related disorders and diseases that are diagnosed during early childhood, such as diabetes, autism, childhood cancer, and obesitas, is very limited. Within this research area, a significant number of studies have been conducted, but it is impossible to draw firm conclusions due to methodological limitations, including the retrospective assessment of exposure, inadequate

data on exposure status and/or outcomes, and lack of study power. The design of the PRIDE Study will overcome these methodological shortcomings. For a more detailed description of the background of the PRIDE Study, please see the study protocol.

Study objective

The primary objective of the PRIDE Study is to identify factors to which a woman is exposed during her pregnancy that have an influence on the health status of the mother and/or her (unborn) child. In addition, the evaluation of preconception, prenatal, and perinatal care in the Netherlands (counselling, screening, prenatal diagnostic procedures, etc.) is an important aim within the PRIDE Study. Three specific objectives for the PRIDE Study have been formulated: (1) to describe the distribution of determinants during pregnancy and to estimate incidences and prevalences of various outcomes, (2) to evaluate preconception, prenatal, and perinatal care in the Netherlands, and (3) to study which prenatal factors influence maternal and/or child health.

Study design

Prospective cohort study. Smaller cohorts of women with a specific exposure, such as use of medication and working with chemical pesticides, will be followed in more detail, and will possibly be asked to provide blood samples. The data collection will primarily be conducted using web-based questionnaires. The participants will be asked to complete a questionnaire at gestational weeks 8-10, 17, and 34, as well as 6 months after the estimated date of delivery.

Study burden and risks

De belangrijkste belasting voor de deelnemende vrouwen bestaat uit het 4 maal (digitaal) invullen van een vragenlijst, hetgeen 10 to 20 minuten per keer zal kosten. Daarnaast kan eventueel nog een voedingsvragenlijst worden ingevuld en de partner vult eenmalig een vragenlijst in met een gelijke tijdsbelasting. Een deel van de vrouwen zal ook gevraagd worden eenmalig deel te nemen aan een bloedonderzoek, dat ofwel gelijktijdig met het bloedonderzoek voor de zwangerschapscontrole plaatsvindt ofwel een aparte bloedprik vereist. Er bestaan geen risico*s voor vrouwen die uitsluitend deelnemen aan het vragenlijstonderzoek. De overige vrouwen lopen alleen enig (verwaarloosbaar) risico bij de standaard bloedafname (3 extra buisjes) of bij de extra bloedafname t.b.v. de PRIDE Study.

De main burden for the participating women consists of completion of 4 questionnaires which will cost 10 to 20 minutes each. In addition, a food frequency questionnaire can be filled out and the partner completes one questionnaire of approximately the same lenght. Part of the women will also be asked to donate 3 blood samples which will be drawn at the same time as the

regular blood samples for the pregnancy check-up or be means of an extra blood draw. There are no risks for women who participate in the questionnaire study only. The other women run a negligible risk at the standard or extra blood draw.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- living in the Netherlands
- female
- pregnant for less than 17 weeks

Exclusion criteria

- knowledge about pregnancy outcome

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2011
Enrollment:	150000
Type:	Actual

Ethics review

Approved WMO Date:	05-10-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-07-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-03-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL30672.091.09