The effects of pregnancy on the human brain

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

Summary

ID

NL-OMON43856

Source
ToetsingOnline

Brief title
PHB

Condition

- Other condition

Synonym
n.v.t.

Health condition

de focus is op de effecten van een gezonde zwangerschap

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Leiden
Source(s) of monetary or material Support: Veni beurs (451-14-036;"The effects of pregnancy on the human brain")

Intervention

Keyword: Brain, Hormones, Plasticity, Pregnancy

Outcome measures

Primary outcome

We will apply structural Magnetic Resonance Imaging, Diffusion Tensor Imaging , Magnetic Resonance Spectroscopy as well as several functional Magnetic Resonance Imaging paradigms to investigate regional tissue volumes, white matter tracts, metabolite concentrations and neural activity during rest and the performance of tasks targeting social cognition and verbal memory. In addition, the participants will perform a battery of computerized tasks, and salivary/urinary hormonal and physiological measures will be obtained.

Secondary outcome

n.a.

Study description

Background summary

During pregnancy, the body and brain are exposed to an unequaled flood of sex steroid hormones. In non-human animals, this period is known to involve substantial alterations in neural architecture. In humans, very little is known on the effects of pregnancy on the brain. In a previous prospective study, extensive and long-lasting changes in grey matter volume were observed after pregnancy, which were primarily located in higher-order associative areas subserving social cognition. The current proposal will further examine the way

the human brain is altered by the biological process of pregnancy.

Study objective

The proposed study will further examine the effects of pregnancy on the human brain, by investigating structural and functional connectivity, local metabolite concentrations and neural activity related to social cognitive and memory processes. Furthermore, this study aims to relate the neural changes of pregnancy to specific hormones and changes in behavioral or physiological measures.

Study design

This topic will be investigated using a prospective within-subjects case-control setup, in which women with the intention to get pregnant in the near future will be examined to obtain a pre-pregnancy baseline and will be followed into early maternity. In addition, a group of control women with no such intention in the near future will also be examined longitudinally. All measurements are non-invasive.

Study burden and risks

There are no known risks associated with this research project.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Healthy women with no history of neurological disorders
2. The intention to become pregnant (experimental group) or not (control group) in the near future
3. No intracranial or intraocular metal or a pacemaker
3. Native Dutch speakers

Exclusion criteria

1. A history of neurological disorders
2. Intracranial or intraocular metal, pacemaker, claustrophobia

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-06-2016
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	06-04-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL55324.058.15