Magnetic resonance imaging (MRI) for assessing fetal and neonatal brain development in the YOUth Cohort.

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

Summary

ID

NL-OMON55467

Source
ToetsingOnline

Brief title
Fetal and neonatal MRI.

Condition

- Other condition

Synonym
behavior, brain

Health condition

Hersen-, neurocognitieve- en gedragsontwikkeling

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W,Nutricia

Intervention

Keyword: Birth cohort, Brain development, Cerebral ultrasound, MRI

Outcome measures

Primary outcome

A comprehensive examination of the developing brain will be carried out using T1, T2, DTI, SWI, PC-MRI and fMRI-derived (micro)structural and functional parameters: brain volumes, cortical thickness, cortical folding, white matter connectivity, hemodynamics and functional networks.

Secondary outcome

Structural and functional parameters of the developing brain will be linked to long-term neurocognition and behavioral outcome, i.e. behavioral control and social competence as examined in the YOUth Cohort.

Study description

Background summary

The human brain is the result of an elaborate developmental trajectory of its evolving neurons, axons, dendrites, volumetric growth as well as macroscale (trans)formation of its neuronal wiring architecture. Most important maturational and morphological changes occur during the last trimester of pregnancy (between 29 and 40 weeks), but normal development of brain architecture between the beginning of the last trimester of pregnancy and immediately after birth is sparsely described in vivo.
One of the purposes of YOUth is to explain how brain development mediates neurocognitive outcome in children, but high-resolution neuroimaging data of the fetal and neonatal brain are missing. To complement the whole range of neurocognitive developmental determinants as measured in YOUth, this study will

explore longitudinal structural and functional maturation of the fetal and neonatal brain using magnetic resonance imaging (MRI). Findings on dynamic variation in (micro)structure, cortical volume, cortical folding and surface, functional and structural connectivity using longitudinal MRI with refined data analyzing methods would be of great importance for our understanding of brain maturation. It will be of additional value to link early structural and functional neurodevelopment to later life cognitions, behavioral control and social competence as measured in the longitudinal YOUth study.

Study objective

This study aims to analyze (micro)structural and functional brain development between the early last trimester fetal and neonatal period with the use of longitudinal MRI sequences and sophisticated post-acquisition processing techniques. Subsequently, we aim to find a relation between structural and functional brain development and long-term neurocognition and behavioral outcome as examined in the YOUth study.

Study design

The current fetal and neonatal MRI study will be an extension of the longitudinal YOUth baby and child study. Pregnant mothers will be invited to undergo an MRI scan. This first MRI scan takes place in utero at 30 to 34 weeks of gestation and the second MRI and ultrasound within the three months after birth. Each MRI scan will include at least T1 weighted and T2, DWI, DTI, SWI, PC-MRI and rs-functional MRI sequences.

Study burden and risks

The information gained from this study will attribute to the scientific knowledge of pre- and neonatal development of the human brain and cannot be examined in adults. The burden for both the mother and the newborn child is the experience of undergoing an MRI scan and ultrasound. There is no direct benefit or significant-risk for the subjects, when normal precautions are taken by our experienced staff (e.g. hearing protection, no metal). Current experimental and clinical evidence indicates that there are no adverse biological effects for pregnant women, fetuses and neonates from the use of MRI.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Babies and toddlers (28 days-23 months)
Newborns

Inclusion criteria

Subject is included in the YOUth Cohor study, has a good understanding of the Dutch language and has signed informed consent.

Exclusion criteria

Subject meets any of the exclusion criteria of the YOUth Cohort study. Subject and partner do not wish to be informed about unexpected fetal or neonatal MRI findings with therapeutic consequences. Subjects are not willing to provide informed consent. Subject experiences problems during the MRI scan or does not adhere to instructions of the MRI team.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-01-2018
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	09-11-2016
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	22-03-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-11-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-12-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	01-07-2020
Application type:	Amendment
Review commission:	METC NedMec

Approved WMO Date:	17-06-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	28-06-2022
Application type:	Amendment
Review commission:	METC NedMec

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	NL56837.041.16