

The effects of prenatal exposure to nicotine and cannabis on brain development at school age

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What are the long-term consequences of prenatal exposure to cannabis and nicotine on the brain development of 6-year old children?

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

Summary

ID

NL-OMON35422

Source

ToetsingOnline

Brief title

Prenatal nicotine and cannabis exposure and brain development

Condition

- Other condition
- Structural brain disorders

Synonym

brain development, consequences of cannabis use

Health condition

gebruik van sigaretten en softdrugs tijdens de zwangerschap

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Stichting Vrienden van het Sophia Kinderziekenhuis

Intervention

Keyword: brain development, cannabis, children, nicotine

Outcome measures

Primary outcome

Primary study parameters are intracranial volume, total brain volume, ventricular and lobar volume, grey and white matter volumes volumes of several subcortical structures, such as hippocampus and amygdala. Furthermore, we will measure cortical thickness and fractional anisotropy. Third parameter is the (standard) scores of the children on the various neuropsychological tasks.

Secondary outcome

Not applicable

Study description

Background summary

Three to 4 percent of the Dutch population is currently using cannabis. This is 9% in younger population (Trimbos, 2003).

This means that there is a large group of women of child-bearing age that are using cannabis. Cannabinoids have an influence on the (brain) development of a fetus. Also, smoking during pregnancy has a clear influence on the (brain) development of the fetus. Yet, it is unclear what the long-term effects are of prenatal exposure to cannabis and nicotine on the brain of a young child. We hypothesise that:

- children with prenatal nicotine exposure to have smaller total brain volumes than children not exposed to drugs in utero;
- children with prenatal cannabis exposure to have smaller total brain volumes

than children exposed to cigarette smoking or non-drug-exposed children.

Study objective

What are the long-term consequences of prenatal exposure to cannabis and nicotine on the brain development of 6-year old children?

Study design

This is a non-therapeutic, observational MRI study. Before making the MRI, there is a practice session with a mock scanner. The practice session is aimed at reducing possible fear by preparing the child for the MRI. They get acquainted with the scanner, the scan noises and learn to lay as motionless as possible during the scans. Furthermore, it is emphasized that the child can end the scanning procedure by one push on a button. After the practice session, the following MRI sequences are made; 3D T1 weighted scan, DTI scan and a T2 weighted scan. Furthermore, all children will perform a neuropsychological testbattery.

We compare 3 groups. The cannabis group is compared to the reference group of non-exposed children. The nicotine group is compared to the reference group. The cannabis group is also compared to the nicotine group to study the effects of cannabis while controlling for the effects of smoking.

Study burden and risks

There are no known medical risks associated with an MRI. As the study concerns children, there is an extensive practice protocol aimed at making the procedure as enjoyable as possible. During practising (one session, but more session are also possible) the child is acquainted with the scanner, the scan room and scan noises. At multiple moments, the child is asked whether he/she enjoys the procedure and if he/she is scared. This is a clear opportunity for the child to (non-verbally) express a desire to stop the procedures. The researcher will also during the practice procedure and the MRI scan assess continually if the procedure should be stopped. The procedure will be stopped immediately if the child, the parents or the researcher wish it so. During the practice session and during the MRI will the child be able to watch cartoons. There will be several DVDs for the child to choose from to watch during the MRI and not be bored.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Children (2-11 years)

Inclusion criteria

Prenatal exposure to nicotine or cannabis.
6 years old.
Informed consent by the parents.

Exclusion criteria

Head trauma with loss of conscience
Presence of metal objects in or around the body
Not wanting to be informed of incidental findings

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): 04-09-2009

Enrollment: 180

Type: Actual

Ethics review

Approved WMO

Date: 18-09-2008

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 20-01-2010

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 02-02-2010

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL20910.078.08