Onderzoek naar de gevolgen van aangeboren cytomegalovirus infectie in Nederland.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22019

Source
NTR

Brief title
CROCUS-study

Health condition

Congenital Cytomegalovirus (CMV)infection / Aangeboren CMV infectie
Sensorineural Hearing Loss / Perceptief gehoorsverlies

Sponsors and support

Primary sponsor: - National Institute for Public Health and the Environment (RIVM)
- Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Strategic Research RIVM (SOR)

Intervention

Outcome measures

Primary outcome

Sensorineural Hearing Loss (at the age of 5 or 6 years) determined by audiometric testing in

an audiological center.

Secondary outcome

1. Visual impairment (at the age of 5 or 6 years and in early childhood) determined by visual testing with Landolt-C-test during preventive health check (5-6 yr) and ‘VOV’-test, APK-TOV-test and Landolt-C-test during the child health centre visits (0-4 yr);

2. Cognitive impairment (at the age of 5 or 6 years and in early childhood) determined by a parent development questionnaire (CDI: child development inventory) and school results from the student tracking system (5-6 yr) and by the ‘van Wiechenonderzoek’ during the child health centre visits (0-4 yr);

3. Motor impairment (at the age of 5 or 6 years and in early childhood) determined by a parent development questionnaire (CDI: child development inventory), the Baecke-Fassaert motor test during preventive health check (5-6 yr) and by the ‘van Wiechenonderzoek’ during the child health centre visits (0-4 yr);

4. Sensorineural Hearing Loss (during neonatal hearing screening) determined by audiometric testing in an audiological center (< 1 yr);

5. Growth: Height and weight measurement during the preventive health check (5-6 yr) and the child health centre visits (0-4 yr).

Study description

Background summary

Retrospective Observational Cohort study on the burden of disease of congenitale cytomegalovirus infecton.

Phase 1. Testing of 25.000 dried blood spots of children (4 to 5 years old), with informed consent of parents, on congenital cytomegalovirus infection using polymerase chain reaction (PCR).

Phase 2. Inclusion of 100 children with congenital cytomegalovirus and 200 controls and determining the long term sequelae using information from parents and youth health care.

Study objective

Congenital cytomegalovirus infection can cause long term sequelae including hearing loss and cognitive impairment.

Study design

Retrospective collection of data:

1. At the age of 5 or 6 years;

2. During early childhood (< 4 years);

3. At neonatal screening.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Phase 1:

1. Children between 4 and 5 years of age, born between January and September 2008 and living in the Netherlands, whose DBS from the neonatal screening are stored for 5 years.

Phase 2:

1. All children with congenital CMV infection, established by a positive PCR analysis for CMV in the DBS from the neonatal screening;

2. A (twice as large) control group of children without congenital CMV infection, established by a negative PCR analysis for CMV, matched for age (month of birth), gender and region.

Exclusion criteria

Phase 1:

1. Children who did not participate in neonatal screening;

2. Children whose dried blood spots are not stored for 5 years;

3. No informed consent from one of the parents (or the legal representative if applicable).

Phase 2:

1. No informed consent from both parents (or the legal representative if applicable);

2. Children with missing data of the PCR for CMV on the DBS.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	17-09-2012
Enrollment:	300
Type:	Actual

Ethics review

Positive opinion
Date: 16-08-2012
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39637
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3431
NTR-old	NTR3582
CCMO	NL39787.058.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39637

Study results

Summary results
N/A