Onderzoek naar de gevolgen van aangeboren cytomegalovirus infectie in Nederland.

Gepubliceerd: 16-08-2012 Laatst bijgewerkt: 19-03-2025

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22019

Bron
Nationaal Trial Register

Verkorte titel
CROCUS-study

Aandoening

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

Ondersteuning

Primaire sponsor: - National Institute for Public Health and the Environment (RIVM)
- Leiden University Medical Center (LUMC)
Overige ondersteuning: Strategic Research RIVM (SOR)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Retrospective collection of data:

1. At the age of 5 or 6 years;

2. During early childhood (< 4 years);

3. At neonatal screening.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	17-09-2012
Aantal proefpersonen:	300
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	16-08-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39637
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A