The state of the nervous system, psychology and eyes of HIV-infected children in comparison to healthy children.

Gepubliceerd: 12-07-2013 Laatst bijgewerkt: 13-12-2022

HIV-infection and antiretroviral therapy use may lead to a diminished neurological and neurocognitive performance in HIV-infected children.

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

Samenvatting

ID

NL-OMON20039

Bron
NTR

Verkorte titel
NOVICE

Aandoening

HIV, neuropathology, AIDS, children, co-morbidities of antiretroviral therapy

Ondersteuning

Primaire sponsor: University of Amsterdam
Overige ondersteuning: Steun Emma Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Neuropsychological performance
MRI/MRS- white matter abnormalities, cerebral perfusion, metabolite concentrations
Ophthalmological assessment outcomes
Optical Coherence Tomography outcomes

Toelichting onderzoek

Achtergrond van het onderzoek

ationale: Before the era of combined antiretroviral therapy (cART), perinatally infected HIV-positive children
frequently presented with serious neurological dysfunctioning (prevalence varying from 30%-50%), including
HIV-encephalopathy, as characterized by impaired brain growth and acquired microcephaly, symmetrical
motor deficits and loss of or failure to attain developmental milestones1. Early neuroimaging studies of HIVencephalopathy
using computed tomography (CT) demonstrated cerebral atrophy, calcifications in the basal ganglia and white matter changes2. Since HIV-infected children are being treated with cART, the incidence of
HIV-encephalopathy has decreased while in the meantime neuro-imaging abnormalities shown by these
conventional neuroimaging techniques have improved1. Children can present with other neurologic disorders
such as seizures, headaches and neurocognitive impairments (e.g. learning-, behavioural-, and motor deficits)3.
The etiology of this neurocognitive impairment is complex and, most likely, not purely biologically determined.
Environmental factors, such as home environment and socioeconomic status (SES), may play a confounding
role in cognitive development4. In our patient group, the SES is generally lower than in the average population.
Comparative data on neurological and neurocognitive findings between HIV-infected and healthy controls with
equal SES and living within similar environments are lacking.
Since neurological and neurocognitive disorders cannot be diagnosed until they are clinically obvious, the
availability of objective, reliable, non-invasive markers may offer great advantages in assessing early central
nervous system (CNS) involvement in HIV-positive children. Standardized neuropsychological assessment (NPA)
and several advanced neuroimaging tests as well as ophthalmological measurements are available to study the
neurological, neurocognitive and ophthalmological disorders in HIV-positive children. In

addition, biochemical
tests and measurement of cART concentration levels in cerebrospinal fluid (CSF) and blood, and combining
these results with the earlier mentioned NPA, neuroimaging and ophthalmological tests, will provide more
insight in the pathophysiology of CNS involvement of HIV and its clinical consequences.

Doel van het onderzoek

HIV-infection and antiretroviral therapy use may lead to a diminished neurological and neurocognitive performance in HIV-infected children.

Onderzoeksopzet

Cross-sectional

Onderzoeksproduct en/of interventie

None (observational study)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Confirmed HIV-1 infection (cases only)

8-18 years of age

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Trauma >30 minutes

Intracranial malignancy

Severe psychiatric disorders

MRI contra-indications

Onderzoeksopzet

Opzet

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

Deelname

Nederland
Status: Werving gestart

(Verwachte) startdatum:	28-12-2012
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-07-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3877
NTR-old	NTR4074
Ander register	: NOVICE
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A