Neurologische en cognitieve ontwikkeling bij kinderen die vanaf de geboorte hiv geïnfecteerd zijn

No registrations found.

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

Summary

ID

NL-OMON26552

Source NTR

Brief title NOVICE II

Health condition

Hiv infectie

Sponsors and support

Primary sponsor: AIDSfonds Source(s) of monetary or material Support: AIDSfonds

Intervention

Outcome measures

Primary outcome

difference in neurocognitive functioning compared to baseline visit (NOVICE I)

Study description

Background summary

Despite combination antiretroviral therapy (cART), perinatally HIV (PHIV)-infected children present with significant neurodevelopmental delays and cognitive impairments. The pathogenesis may partially differ from that in adults, as HIV does not only cause direct injury to the CNS, but may also impede the development of the pediatric brain. As we have recently shown, manifestations of HIV in the pediatric central nervous system (CNS) include brain volume reduction and white matter lesions, as well as widespread microstructural changes, such as poorer white matter integrity and alterations in cerebral metabolites. Evidence implies significant roles for ongoing neuroinflammation, vascular dysfunction and hypercoagulability. Investigations combining neuropsychological assessment, multimodal neuroimaging and laboratory evaluation of inflammatory and neurodegenerative markers could greatly increase our understanding and improve treatment strategies. Longitudinal research will be crucial to observe and understand mechanisms underlying these long-term consequences of CNS exposure to HIV and cART as PHIV-infected survive into adulthood. In this study we will evaluate neurological and cognitive outcomes in a case-control cohort of PHIV infected children and sex, ethnicity and socioeconomic status matched healthy controls at an interval period of four years. We will investigate potential mechanisms and factors (such as inflammatory and neuronal biomarkers) that may influence these CNS functions.

Study design

Second measurement after 4-5 years. These measurements are cross sectional.

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

Children between 8-22 years of age, perinatally infected with hiv.

Together with healthy controls, machted with the infected group for gender, age, socioeconomic status and ethnicity.

Exclusion criteria

chronic neurological disorders like epilepsy, intracerebral neoplasms and psychiatric disorders

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Other
Start date (anticipated):	23-05-2017
Enrollment:	100
Туре:	Unknown

Ethics review

Positive opinion

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Date: Application type:

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
NTR-new	NL6813
NTR-old	NTR7000
Other	METC : 2016-173

Study results