Study on Sophia HIV infected Children Cohort

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1. Evaluation of neurocgnitive functioning in children with HIV in comparison with healthy siblings using questionnaires.2. Qualitative analysis of different determinants that play a role in school participation in children with HIV using interviews...

Ethical review	Approved WMO
Status	Pending
Health condition type	Immunodeficiency syndromes
Study type	Observational invasive

Summary

ID

NL-OMON45152

Source
ToetsingOnline

Brief title
Sophia TREVI study

Condition

- Immunodeficiency syndromes
- Viral infectious disorders
- Central nervous system infections and inflammations

Synonym
HIV associated Neurocognitive disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Children, Coagulation, HIV, Neurocognitive disease

Outcome measures

Primary outcome

Interviews:

Parents and children are invited to participate in the interview, which lasts about 25 minutes. The main topics discussed are school participation and neurocognitive functioning.

In vitro analysis:

A side from the routine virologic, immunologic and additional measurements, we want to draw 2 additional tubes. The following parameters are assessed:

* tissue factor expression on monocytes
* Endogeneous thrombine potential (ETP)
* Fibrine 1+2
* Prothrombine time
* van Willebrand factor
* ATIII
* Protein S
* Plasmine-antiplasmine complex
* D-dimer
* Interleukin 6

* Circulating endothelial cells

MRI

MRI imaging will be performed on a 3.0 Tesla MR unit. The following structures will be assessed: white vs grey matter, hippocampus, cortical size and presence of focal leasions.

Cortisol in hair

Measurement of cortisol in hair is an validated technique since recently. We will take a small amount (10-100 hairs) from the back of the scalp.

Amendment: Circulating Endothelial Cells.

Secondary outcome

not aplicable

Study description

Background summary

With the de development of combination antiretroviral therapy (cART or HAART), the mortality and morbidity for children with HIV has decreased drastically. In addition, the presence of neurologic and neuropsychologic complications have decimated. However, there are still subtle cognitive disorders found in patients with HIV. This could have consequences for school participation and results. The cause of these disorders have only been elucidated partly and deserve more investigation.

Study objective

1. Evaluation of neurocgnitive functioning in children with HIV in comparison with healthy siblings using questionnaires.

2. Qualitative analysis of different determinants that play a role in school participation in children with HIV using interviews with the children and parents.
3. Qualitative analysis of relation between neurocognitive functioning and school participation in children with HIV using questionnaires and interviews.
4. Evaluation of endocrine, coagulation and immune parameters in blood and association with neurocognitive performance, MRI and cerebral spinal fluid analysis.

Amendment; because of interesting results in the laboratory experiments (Circulating Endothelial Cells), we would like to add a HIV-seronegative control population. We believe it is ethically preferred to obtain samples from a control group that has already agreed to donate blood. It is not possible to use the data we previously obtained from healthy uninfected adults.

Study design

Children and parents will be subjected to interviews and questionnaires by drs. van Opstal. Siblings will also be recruited since they could act as controls. Abnormal findings will be discussed with the clinical neuropsychologist (dr. F. van Aarsen) the pediatric infectiologist (dr. van Rossum) and nurse specialist (ms. van der Knaap). Additional investigations (e.g. MRI or cerebral spinal fluid tap) will only be performed after consensus has been reached. Also, in vitro investigation will be performed with blood products (PBMC's and plasma). All the other parameters (e.g. viral load and CD4) will be performed as routinely planned. We will combine the sampling as much as possible so that no additional venapunctures are required.

Amendment: control patients will be matched on age, sex and (if possible) on ethnicity. Sample collection will take place during planned venapuncture for the Sophia Biobank study (MEC: 2013.381). We aim to collect 14,5ml of blood (10ml EDTA and 4,5ml Citrate)

Study burden and risks

The questionnaires will take about 25-40 minutes (it differs per age group and if parent, patient or sibling), see protocol page 16.
We will invite the parent and patient for an interview of about 25 minutes.

Amendment: a single extra sample collection during planned venapuncture.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Patiënt population:
- Age 4 -20
- Dutch or Eglish speaking
- HIV-infection
- Currently under treatment at Sophie Children's Hospital;Siblings:
- Age 4-20
- Dutch or English sprekend
- No HIV-infection
- Currently living in one household with patient
- Living for at least 3 years with patient;Parents:
- Dutch or English speaking
- Care giver of patient for at least 3 years;Teachers
- Dutch or English speaking

- Elementary or high school teacher of patient

Exclusion criteria

Patiënt population:
- Younger than 3 years of age
- Currently end of treatment at Sophia Children's Hospital
- History of opportunistic infection of Central Nervous system
- History of schizophrenia
- History of chronic neurological disorders like epilepsy or multiple sclerosis
- Affective disorder, reasonably causing cognitive deficits ;Siblings:
- Age below 4 years or above 20 years
- Not living in one household with patient
- Living less than 3 years with patient in one household
- History of opportunistic infection of Central Nervous system
- History of schizophrenia
- History of chronic neurological disorders like epilepsy or multiple sclerosis
- Affective disorder, reasonably causing cognitive deficits ;Parents:
- Not Dutch or English speaking;Teachers:
- Not Dutch or English speaking

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2013
Enrollment:	92
Type:	Anticipated

Ethics review

Approved WMO Date:	04-03-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-01-2017
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	NL45108.078.13