

# Liver Toxicity in children with HIV Infections, case controle study (LITHI study)

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The objective of this study is to gain insight in HIV infected children in the AMC in:- the prevalence and clinical signs of livertoxicity - an association between the different compounds of combination anti-retroviral therapy (cART) and...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Hepatic and hepatobiliary disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON35883

### Source

ToetsingOnline

### Brief title

LITHI study

### Condition

- Hepatic and hepatobiliary disorders
- Viral infectious disorders

### Synonym

liverdisease, livertoxicity

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** Stichting tot Steun Emma Kinderziekenhuis

## Intervention

**Keyword:** children, HIV, livertoxicity

## Outcome measures

### Primary outcome

livertoxicity

### Secondary outcome

n.a.

## Study description

### Background summary

Livertoxicity in HIV infected patients has been associated with the combination treatment these HIV infected patients use, the HIV infection itself and various other viruses such as hepatitis C.

In the AMC we have recently discovered that in four out of the 56 HIV infected children, various degrees of livertoxicity were noted. Because of the high incidence of this serious disorder in our population and the lack of symptoms of the HIV infected children with livertoxicity, we think it is necessary to screen all HIV infected children. For an appropriate comparison, we will compare livertoxicity in HIV infected children with children without an HIV infection.

### Study objective

The objective of this study is to gain insight in HIV infected children in the AMC in:

- the prevalence and clinical signs of livertoxicity
- an association between the different compounds of combination anti-retroviral therapy (cART) and livertoxicity
- correlations between biochemical markers and non-invasive ultrasonography for the detection of livertoxicity in HIV infected children

### Study design

After written informed consent, 10 cc of blood will be taken from HIV infected children and tested for biochemical markers of livertoxicity. Furthermore two

different ultrasound of the liver will be performed, one standard ultrasound and one elastography of the liver. The study is finished after these tests.

### **Study burden and risks**

see above

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adolescents (12-15 years)  
Adolescents (16-17 years)  
Children (2-11 years)

### **Inclusion criteria**

Cases are 56 HIV infected children < 18 years of age that are currently being treated in Emma Children's Hospital AMC Amsterdam.

Controles are sex, ethnicity and age matched children without a HIV infection with functional abdominal pains and in whom (because of standard patient care) blooddrawings and abdominal ultrasound investigations are planned or healthy siblings of HIV infected children. For both groups written informed consent is needed

## Exclusion criteria

none

## Study design

### Design

Study type:	Observational non 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):	01-07-2011
Enrollment:	0
Type:	Anticipated

## Ethics review

Approved WMO	
Application type:	First submission
Review commission:	METC Amsterdam UMC

## 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	NL35404.018.11