

# Audiological evaluation of children with HIV

<b>Submission date</b> 25/01/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/01/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/01/2019	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

People infected with the human immunodeficiency virus (HIV) are more likely to have hearing loss, as shown by some previous studies. However, there is no consensus about the age of hearing impairment, type of hearing loss and the real role of characteristics such as viral load (amount of virus in the blood) and the T CD4 cell count (number of an important type of cells of defense). The aim of this study is to assess the hearing status of children with HIV.

### Who can participate?

Children with HIV aged 18 months to 11 years treated at a university hospital in Brazil, and children without HIV for comparison

### What does the study involve?

Information on ear complaints (like ear infection, ear pain, difficulty in hearing, tinnitus, difficulty in word discrimination, and feeling of fullness in the ear), type and duration of antiretroviral therapy, viral load, and CD4+ cell count are obtained from the child's caregiver. An ear examination and hearing test are performed.

### What are the possible benefits and risks of participating?

The main benefit for the children involved was the early detection of hearing loss. The risks for participants were a little pain during the ear examination and hearing test if they moved their head.

### Where is the study run from?

Hospital of the Federal University of Maranhão (Brazil)

### When is the study starting and how long is it expected to run for?

April 2015 to September 2018

### Who is funding the study?

FAPEMA (Fundação de Amparo à Pesquisa e ao Desenvolvimento Científico e Tecnológico do Estado do Maranhão)

### Who is the main contact?

Prof. Janaína Pulcherio

# Contact information

## Type(s)

Scientific

## Contact name

Prof Janaina Pulcherio

## Contact details

Praça Gonçalves Dias, 21  
São Luís  
Brazil  
65020240

# Additional identifiers

## Protocol serial number

1.175.254/2015

# Study information

## Scientific Title

Transient evoked otoacoustic emission in children infected with human immunodeficiency virus

## Study objectives

HIV causes hearing loss.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethical Research Committee of Health Ministry of Brazil, Barão de Itapary Street, number 227, District: CENTER, São Luís, Maranhão, Brazil, Tel: +55 (98)2109-1250, Email: cep@huufma.br, 07/08/2015, protocol number 1.175.254/2015

## Study design

Cross-sectional observational study

## Primary study design

Observational

## Study type(s)

Diagnostic

## Health condition(s) or problem(s) studied

HIV infection

## Interventions

Data on complaints (like otorrhea, ear pain, difficulty in hearing, tinnitus, difficulty in word discrimination, and feeling of fullness in the ear), type and duration of antiretroviral therapy, viral load, and CD4+ cell count were obtained from the caregiver. Otoscopy and transient evoked otoacoustic emission (TEOAE) testing were then performed.

## **Intervention Type**

Other

## **Primary outcome(s)**

Assessed at a single timepoint:

1. Otologic complaints (like otorrhea, ear pain, difficulty in hearing, tinnitus, difficulty in word discrimination, and feeling of fullness in the ear) assessed using caregiver interview
2. Ear anatomy assessed using otoscopy
3. Hearing assessed using transient evoked otoacoustic emission (TEOAE) testing

## **Key secondary outcome(s)**

Assessed at a single timepoint:

1. Viral load, assessed using caregiver interview (the last test performed)
2. CD4+ cell count, assessed using caregiver interview (the last test performed)
3. Details of anti-retroviral therapy, assessed using caregiver interview

## **Completion date**

30/09/2018

# **Eligibility**

## **Key inclusion criteria**

1. Children living with HIV aged 18 months to 11 years
2. Attending the Hospital of the Federal University of Maranhão, in Northeast Brazil

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Child

## **Lower age limit**

18 months

## **Upper age limit**

11 years

## **Sex**

All

## **Key exclusion criteria**

1. Family history of deafness
2. Consanguineous parents
3. Psychomotor developmental delay due to neurological disease
4. Craniofacial anomalies
5. Prematurity
6. Hospitalization to a neonatal intensive care unit
7. Meningitis
8. Treatment with chemotherapy
9. Perinatal co-infection (toxoplasmosis, rubella, cytomegalovirus, syphilis, herpes, HTLV-1, or viral hepatitis B and C), acute infection (external or middle ear)
10. Child uncooperative or aggressive

**Date of first enrolment**

01/05/2016

**Date of final enrolment**

30/06/2018

## Locations

**Countries of recruitment**

Brazil

**Study participating centre**

**Hospital of the Federal University of Maranhão**

Barão de Itapary Street, number 227, District: Center

São Luís, Maranhão

Brazil

65020240

## Sponsor information

**Organisation**

FAPEMA

**ROR**

<https://ror.org/03vqm2n93>

## Funder(s)

**Funder type**

Government

**Funder Name**

FAPEMA

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Janaina Pulcherio ([janabentivi.ori@gmail.com](mailto:janabentivi.ori@gmail.com)).

### **IPD sharing plan summary**

Available on request