

Audiological evaluation of children with HIV

Submission date 25/01/2019	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/01/2019	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 28/01/2019	Condition category Infections and Infestations	☐ Individual participant data ☐ 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

Primary study design

Observational

Study design

Cross-sectional observational study

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).

IPD sharing plan summary

Available on request