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Audiological evaluation of children with HIV

Submission date	Recruitment status	[_] Prospectively registered
25/01/2019	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/01/2019	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/01/2019	Infections and Infestations	[_] 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
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Brazil
65020240

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

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 measure
Assessed at a single timpepoint:
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

Secondary outcome measures
Assessed at a single timpepoint:
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

Overall study start date
01/04/2015

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

Age group
Child

Lower age limit
18 Months

Upper age limit
11 Years

Sex
Both

Target number of participants
40

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

Sponsor details
Perdizes Street, number 05, square 37, District: Jardim Renascença
SÃO LUÍS, MARANHÃO
Brazil
65075340

Sponsor type
Government

Website
http://www.fapema.br/

ROR
https://ror.org/03vqm2n93

Funder(s)

Funder type
Government

Funder Name
FAPEMA

Results and Publications

Publication and dissemination plan
The trialists intend to publish at BMC Medicine.

Intention to publish date
01/02/2019

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.orl@gmail.com).

IPD sharing plan summary
Available on request