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Gentamicin, genetic variation and deafness in preterm children

Submission date
19/12/2013

Recruitment status
No longer recruiting

Registration date
18/02/2014

Overall study status
Completed

Last Edited
28/05/2019

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Acquired hearing loss is a hearing loss that appears after birth. It occurs ten times more often in infants born before 32 weeks of gestation (very preterm). There are several possible causes, including the side effects of some regularly used medications on neonatal units, such as aminoglycosides. These are known to have effects on the hearing system but, despite being at high risk of receiving aminoglycosides, there is little evidence for drug-induced damage to the inner ear in preterm children. The risk of hearing loss may be increased further in babies with the DNA mutation m.1555A>G. Patients with this mutation who receive aminoglycosides suffer from hearing loss even when drug levels are maintained within normal limits; this effect may be reduced in the newborn period, but this has not been formally studied. The aim of this study is to look at the relationship between the m.1555A>G mutation, aminoglycosides and deafness in children born very prematurely.

Who can participate?
Deaf children and children with normal hearing who were born at 31 weeks and 6 days of gestation or less

What does the study involve?
Saliva samples are taken from children in both groups for genetic analysis of m.1555A>G. Clinical data including information on aminoglycoside exposure is taken from medical notes.

What are the possible benefits and risks of participating?
The main benefit to participants with deafness is the opportunity to find the cause of their hearing loss. If the child has the mutation, it is likely that this is the cause. There is little benefit for participants who have normal hearing, but if they test positive for the mutation they are advised to avoid aminoglycoside antibiotics in the future to prevent the risk of hearing loss. There are no anticipated risks for participants, although children could be nervous about having a saliva sample taken.

Where is the study run from?
University College London (UK)

When is the study starting and how long is it expected to run for?
January 2013 to January 2016

Who is funding the study?
Action on Hearing Loss (UK)

Who is the main contact?
1. Prof. Maria Bitner-Glindzicz (maria.bitner@ucl.ac.uk)
2. Prof. Neil Marlow (n.marlow@ucl.ac.uk)

Study website
http://www.ucl.ac.uk/mitogent

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ISRCTNRNIDG47

Study information

Scientific Title
Gentamicin, genetic variation and deafness in preterm children: a case-control study

Acronym
MitoGent

Study objectives

The hypothesis is that mutation (m.1555A>G) makes a significant contribution to deafness in babies born at 31 weeks and 6 days of gestation or less who receive treatment with aminoglycosides, even when drug levels were within the normal range.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Ethics Committee London - Central, 02/02/2012, ref: 12/LO/0005

Study design
Case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
http://www.ucl.ac.uk/mitogent/documents

Health condition(s) or problem(s) studied
Hearing loss in preterm infants

Interventions
This is an observational study which will only involve saliva samples and access to medical notes. Children with hearing loss will be invited to participate by their audiological paediatrician; ex-preterm children with normal hearing will be invited by their neonatologist. Saliva samples will be taken from children in both groups for genetic analysis of m.1555A>G. Clinical data including information on aminoglycoside exposure will be abstracted from medical notes.

Intervention Type
Other

Primary outcome measure
Prevalence of the m.1555A>G mutation, measured using saliva samples tested for the mutation by direct DNA sequencing

Secondary outcome measures
Gentamicin administration, measured using data from medical notes

Overall study start date
27/01/2013

Completion date
27/01/2016

Eligibility

Key inclusion criteria
Cases: babies born at 31 weeks and 6 days gestational age or less with hearing loss, treated on a neonatal unit within Greater London between 01/01/2009 - 31/12/2013
Controls: babies born at 31 weeks and 6 days gestational age or less with normal hearing, treated on a neonatal unit within Greater London between 01/01/2009 - 31/12/2013

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
30 - 60 deaf children and 5 controls per deaf baby/child. Total 150-300 children

Key exclusion criteria
Cases: no exclusion criteria
Controls: missing data in medication records

Date of first enrolment
27/01/2013

Date of final enrolment
27/01/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London - Institute of Child Health
London
United Kingdom
WC1N 1EH

Sponsor information

Organisation
University College London - Institute of Child Health (UK)

Sponsor details
30 Guilford Street
London
England
United Kingdom
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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Charity

Funder Name
Action on Hearing Loss (UK) (ref: RNID G47)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The trialists intend to publish in 2017.

Intention to publish date

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date