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Evaluation of initial fitting of young children using intraoperative neural response telemetry (NRT)

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 07/09/2015	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0045122960

Study information

Scientific Title

Evaluation of initial fitting of young children using intraoperative neural response telemetry (NRT)

Study objectives
How do the two existing methods of mapping cochlear implants, intraoperative neural response telemetry measures and behavioural assessment compare?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cochlear implants

Interventions
Patients are going to be randomised to either intraoperative neural response telemetry (NRT) or initial fitting based on behavioural assessment.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Performance on Infant Toddler Meaningful Auditory Integrated Scale (IT-MAIS)
2. Performance on phonemes differentiation test (APE)
3. Soundfield Threshold Assessment
4. Time spent performing clinical activities involved

Key secondary outcome(s)
Not provided at time of registration

Completion date
01/09/2004

Eligibility

Key inclusion criteria
Children aged <4 years of age with congenital deafness and no cochlear malformations such as dysplasia. Minimum of 10 children.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
4 Years

Sex
All

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
22/10/2002

Date of final enrolment
01/09/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Aston University
Birmingham
United Kingdom
B4 7ET

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Birmingham Children's Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration