

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

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/09/2015	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Study design

Randomised controlled trial

Primary study design

Interventional

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