

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

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| 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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B4 7ET

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

22/10/2002

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

Age group

Child

Upper age limit

4 Years

Sex

Both

Target number of participants

10

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

England

United Kingdom

Study participating centre
Aston University
Birmingham
United Kingdom
B4 7ET

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type
Hospital/treatment centre

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration