

Comparison of BAHA Softband vs conventional hearing aid in management of hearing loss in young children with Down's syndrome

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/08/2012	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
Mr P Sheehan

Contact details
ENT Department
North Manchester General Hospital
Delaunays Road
Manchester
United Kingdom
M8 5RB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0155164513

Study information

Scientific Title

Study objectives

Is BAHA Softband better than conventional hearing aid for children with Down's Syndrome?

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)

Not specified

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

Ear, Nose and Throat: Hearing loss

Interventions

BAHA Softband vs conventional hearing aid

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Improvement in hearing

Secondary outcome measures

Not provided at time of registration

Overall study start date

31/05/2005

Completion date

31/12/2009

Eligibility

Key inclusion criteria

Children with Down's Syndrome aged 24-48 months with mild to moderate hearing loss.

Participant type(s)

Patient

Age group

Child

Lower age limit

24 Months

Upper age limit

48 Months

Sex

Not Specified

Target number of participants

16

Key exclusion criteria

Severe hearing loss.

Date of first enrolment

31/05/2005

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

ENT Department
Manchester
United Kingdom
M8 5RB

Sponsor information

Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details

The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

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

Funder(s)

Funder type

Government

Funder Name

Pennine Acute Hospitals NHS Trust (UK), Own Account, NHS R&D Support Funding

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