

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	☐ Prospectively registered ☐ Protocol
Registration date 29/09/2006	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 30/08/2012	Condition category Ear, Nose and Throat	☐ Individual participant data ☐ Record updated in last year

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
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Improvement in hearing

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

24 Months

Upper age limit

48 Months

Sex

Not Specified

Key exclusion criteria

Severe hearing loss.

Date of first enrolment

31/05/2005

Date of final enrolment

31/12/2009

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

ENT Department

Manchester

United Kingdom

M8 5RB

Sponsor information**Organisation**

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

Funder(s)**Funder type**

Government

Funder Name

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

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration