

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

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

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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

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes