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

Submission date	Recruitment status	Prospectively registered
29/09/2006	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
29/09/2006	Completed	Results
Last Edited	Condition category	Individual participant data
30/08/2012	Ear, Nose and Throat	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

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?

Participant information sheet
Participant information sheet
11/11/2025 No Yes