

Randomised prospective study of treatment methods for middle ear effusions in pre-school children

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 22/02/2010	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr A Maw

Contact details
United Bristol Healthcare Trust
St Michael's Hospital
St Michael's Hill
Bristol
United Kingdom
BS2 8EG
+44 (0)117 921 5411
armaw@doctors.org.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Study objectives

To determine whether immediate intervention with grommet insertion is as effective as watchful waiting in children with glue ear.

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)

Other

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Otitis media

Interventions

1. Early treatment with ventilation tubes (grommets)
2. Watchful waiting for a period of nine months with analysis by intention to treat

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Early surgery significantly reduced behavioural difficulty by 17% and the difference was largely mediated by concurrent hearing loss.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/1994

Completion date

30/09/1997

Eligibility

Key inclusion criteria

1. Children born between April 1, 1991, and Dec 31, 1992,
2. Confirmed bilateral otitis media with effusion (OME)
3. Bilateral hearing impairment of 25-70 dB of at least 3 months' duration

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/04/1994

Date of final enrolment

30/09/1997

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

United Bristol Healthcare Trust
Bristol
United Kingdom
BS2 8EG

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

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.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive South West (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	20/03/1999		Yes	No
Results article	results	01/06/2000		Yes	No
Results article	follow up results	01/02/2009		Yes	No