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

Submission date 23/01/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 22/02/2010	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

C/COM/16-08-93/MAW/F

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