

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
Registration date 23/01/2004	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 22/02/2010	Condition category Ear, Nose and Throat	☐ Individual participant data

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

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Child

Sex

All

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**

United Kingdom

England

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)

Funder(s)**Funder type**

Government

Funder Name

NHS Executive South West (UK)

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?
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