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Trial of alternative regimens in glue ear treatment - effectiveness of surgery for otitis media with effusion in 3.5-7 year olds using multiple developmental and economic measures combined with classical clinical measures

Submission date 17/10/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/10/2000	**Overall study status** Completed	
Last Edited 19/09/2012	**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

Protocol serial number
E203/85

Study information

Scientific Title

Acronym
TRIAL

Study objectives
To assess the benefit of the three main treatments for Otitis Media with Effusion (OME), i.e. Ventilation tube insertion alone, Ventilation tube insertion plus adenoidectomy, Observation + medical management- in terms of:
1. The impact upon the child's life including hearing ability, general health, behaviour and quality of life
2. The relative cost effectiveness of treatment to the NHS particularly in terms of additional benefit conferred by adenoidectomy

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)
Not Specified

Health condition(s) or problem(s) studied
Hearing research

Interventions
1. Ventilation tube insertion alone
2. Ventilation insertion plus adenoidectomy
3. Observation + medical management

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Clinical measures - Otoscopy, audiometry, tympanometry and questionnaire measures, (hearing and predictive factors, general health, economic impact, behavioural assessment and quality of life)

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/12/1997

Eligibility

Key inclusion criteria
Children aged 3.5-7 years having had no previous ear or adenoid surgery, having B+B or B+C2 tympanograms and a bilateral average hearing threshold greater than 20 dB, plus an air-bone gap greater than 10 dB HL.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
Not Specified

Key exclusion criteria
Children with severe general disease, cranio-facial abnormalities, sensori-neural losses, parents with language or literacy problems. A few children are also excluded if a consultant feels it would be unethical to randomise them into the study.

Date of first enrolment
01/04/1994

Date of final enrolment
01/12/1997

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute of Hearing Research
Nottingham
United Kingdom
NG7 2RD

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/04/2012		Yes	No
Protocol article	protocol	01/10/2001		Yes	No