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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

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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Not Specified

### Participant information sheet

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

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/04/1994

### 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

### Age group
Senior

### Sex
Not Specified

### Target number of participants
590

### 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**
England

United Kingdom

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

# Sponsor information

**Organisation**
Medical Research Council (MRC) (UK)

**Sponsor details**
20 Park Crescent
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**Sponsor type**
Research council

**Website**
http://www.mrc.ac.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

### 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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 01/10/2001 | | Yes | No |
| Results article | results | 01/04/2012 | | Yes | No |