

# 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

<b>Submission date</b> 17/10/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 17/10/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/09/2012	<b>Condition category</b> 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

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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, Medical Research Committee and Advisory 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?
<a href="#">Results article</a>	results	01/04/2012		Yes	No
<a href="#">Protocol article</a>	protocol	01/10/2001		Yes	No