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A study to see how best to treat ear discharge in children

Submission date
11/08/2026

Recruitment status
Not yet recruiting

Registration date
14/08/2026

Overall study status
Ongoing

Last Edited
22/10/2026

Condition category
Ear, Nose and Throat

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study looks at the best way to treat ear infections in children when fluid leaks from the ear. This condition is called acute otitis media with discharge. It happens when an infected eardrum bursts and liquid drains out. The study aims to compare two treatments: oral antibiotics and antibiotic ear drops. Researchers want to find out if it is possible to run a larger study in the future and whether parents can use a remote online consent process.

Who can participate?
Children aged 6 months to under 7 years can take part if they have a new episode of ear discharge lasting less than 6 weeks. They must not have had antibiotics recently. Children cannot take part if they have serious illness, complications of ear infections, certain medical conditions of the ear, or allergies to the study medicines.

What does the study involve?
Children will be chosen at random to receive either oral antibiotics or antibiotic ear drops for 7 days. Parents will be contacted by the study team through phone calls and text messages to check how their child is doing and whether the ear discharge has stopped. The design aims to fit around busy family life.

What are the possible benefits and risks of participating?
Children may benefit from treatment that helps clear their ear infection. The study may also help improve care for future families. Risks include possible side effects from antibiotics, such as stomach upset from oral medicines. Ear drops carry very little risk because they are absorbed into the body at low levels. If any problems occur, families can contact the study team.

Where is the study run from?
The study is run from Manchester University NHS Foundation Trust, with clinical work based at Royal Manchester Children’s Hospital.

When is the study starting and how long is it expected to run for?
November 2026 to September 2027

Who is funding the study?
National Institute for Health and Care Research (UK).

Who is the main contact?
Mr Elliot Heward at the Paediatric ENT research office, Royal Manchester Children’s Hospital, e.heward@nhs.net

Contact information

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Scientific, Public

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Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
1012973

Central Portfolio Management System (CPMS)
75834

Sponsor's protocol code number
B02775

Study information

Scientific Title
Management of acute Ear Discharge in Children (MEDIC): a feasibility study

Acronym
MEDIC

Study objectives
1. To see if running a study comparing antibiotics taken by mouth against drop antibiotics into the ear for treating acute otitis media with discharge is possible. The study is using a remote consent and follow up methods which need to be tested before we run a full large scale study. This is called a feasibility study
2. To see if there are any problems using the medications in children and to help find out the number of children that are required for the full large scale study (called sample size calculation)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 19/10/2026, Hampshire B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)2071048260; hampshireb.rec@hra.nhs.uk), ref: 26/SC/0283

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking

Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment, Efficacy, Feasibility

Study type(s)

Health condition(s) or problem(s) studied
Acute otitis media with discharge

Interventions
Control arm: Oral Amoxicillin or Clarithromycin. Amoxicillin dosed by age for 7 days. Clarithromycin doses by weight for 7 days.
Intervention arm: Ciprofloxacin topical drops. One ampule (0.25ml) of 2mg/ml drops twice daily for 7 days.
Follow up for all participants: 14 days

Randomisation: individual online tool

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Amoxicillin, clarithromycin, ciprofloxacin

Primary outcome(s)
Feasibility outcomes:
1. Number of patients referred to the study during recruitment measured using study database at the end of the study
2. Time from referral to remote consultation with research doctor measured using study database at the end of the study
3. Proportion of patients choosing medication collection measured using study database at the end of the study
4. Time from prescription to medication delivery or collection measured using study database at the end of the study
5. Proportion of patients randomised of those referred to the study measured using study database at the end of the study
6. Participant-reported adherence to treatment measured using study database at the end of the study
7. Proportion of patients with complete follow-up data measured using study database at the end of the study
8. Time to cessation of otorrhoea measured using study database at the end of the study

Key secondary outcome(s)
1. Time to cessation of ear discharge (otorrhoea) measured using daily text message question response
2. Resolution of ear discharge measured using questionnaire at day 7 post treatment commencement and day 14 post treatment commencement
3. Pain severity measured using questionnaire at day 7 post treatment commencement and day 14 post treatment commencement
4. Pain duration measured using questionnaire at day 7 post treatment commencement and day 14 post treatment commencement
5. Fever episodes measured using questionnaire at day 7 post treatment commencement and day 14 post treatment commencement
6. Sleep disturbance measured using questionnaire at day 7 post treatment commencement and day 14 post treatment commencement
7. Appetite disturbance measured using questionnaire at day 7 post treatment commencement and day 14 post treatment commencement
8. Complications of infection measured using questionnaire at day 7 post treatment commencement and day 14 post treatment commencement
9. Healthcare interactions measured using questionnaire at day 7 post treatment commencement and day 14 post treatment commencement
10. Adverse drug reactions measured using questionnaire at day 7 post treatment commencement and day 14 post treatment commencement

Completion date
30/09/2027

Eligibility

Key inclusion criteria
Current key inclusion criteria:
1. Children and young people aged ≥6 months and <7 years
2. Unilateral or bilateral otorrhoea
3. New episode of otorrhoea (>6 weeks from previous episode)
4. Otorrhoea duration <6 weeks
5. No prior antibiotic treatment for this episode
6. No antibiotics for other reasons within 6 weeks prior
7. Parent/guardian who can understand written English, Urdu, Arabic, Punjabi or Polish

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Healthy volunteers allowed
No

Age group

Child

Lower age limit
6 Months

Upper age limit
7 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Current key exclusion criteria:
1. Signs of sepsis (requiring hospitalisation)
2. Complications of ear infections (e.g. mastoiditis, facial nerve palsy, brain abscess, meningitis)
3. Significant immunosuppression
4. Known grommet in the affected ear
5. Known cholesteatoma in the affected ear
6. Hypersensitivity to ciprofloxacin *or any member of the quinolone class of antimicrobial agents*
7. Hypersensitivity to amoxicillin *or to any of the penicillins, or history of a severe immediate hypersensitivity reaction to another betalactam agent (e.g. a cephalosporin, carbapenem or monobactam)* and any contraindication to clarithromycin as per section 4.3 of the SmPC (not just allergy)
8. Currently participating in an ear related research study
9. Currently involved or have been involved with a trial which involves antibiotic treatment within the prior 6 weeks

Previous key exclusion criteria:
1. Signs of sepsis (requiring hospitalisation)
2. Complications of ear infections (for example mastoiditis, facial nerve palsy, brain abscess, meningitis)
3. Significant immunosuppression
4. Known grommet in the affected ear
5. Known cholesteatoma in the affected ear
6. Allergy to ciprofloxacin
7. Allergy to both amoxicillin and clarithromycin
8. Currently participating in an ear related research study

Date of first enrolment
16/11/2026

Date of final enrolment
15/09/2027

Locations

Countries of recruitment

United Kingdom

England

Study participating centre
Manchester University NHS Foundation Trust
Cobbett House
Oxford Road
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M13 9WL

Sponsor information

Organisation
Manchester University NHS Foundation Trust

ROR
https://ror.org/00he80998

Funder(s)

Funder type

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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 expected to be made available