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Understanding how infections which cause ear discharge affect children and young people's lives and how they would like it to be treated

Submission date
06/06/2023

Registration date
22/08/2023

Last Edited
03/04/2025

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Ear, Nose and Throat

☐ Prospectively registered
☒ Protocol
☐ Statistical analysis plan
☒ Results
☐ Individual participant data

Plain English summary of protocol

Background and study aims
Ear infections are common in children and young people. During an infection the ear drum can burst, causing infected smelly fluid to leak out of the ear. This fluid is called otorrhoea. If the infection is not treated, the ear may continue to leak for weeks or months. It may also cause hearing loss, which might make it harder for children to develop speech and language skills. Rarely, more serious complications can occur, for example if the ear infection spreads to the bone of the skull and the brain. Despite ear infections and otorrhoea being common in children, we do not know how it affects their lives. Importantly, we also do not know how best to treat it.
1. We want to understand how otorrhoea affects children and young people and their families everyday lives
2. We want to know which treatments children and young people and their carers would prefer and why
3. We want to ask medical professionals their experiences of treating children and young people with otorrhoea

Who can participate?
Children and young people aged 16 years and under who have or have had otorrhoea in the past 1 year & medical professionals who interact with this type of patient.

What does the study involve?
We are going to perform 30 interviews with children and young people with their carers and speak to 24 medical professionals.

What are the possible benefits and risks of participating?
Patients and medical professionals will have satisfaction in knowing they are helping to better the understanding of this health condition. They will be able to have their voices and opinions heard which will help shape future research in this area. Patients will receive a £25 voucher for their time. Medical professionals will be able to cite this activity as professional development and place any publications in their portfolio where they will be acknowledged. We will offer to send participants the research findings at the end of the study.

Where is the study run from?
Manchester University NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
November 2022 to March 2024

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

Who is the main contact?
Dr Elliot Heward, elliotheward@doctors.org.uk
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Contact information

Type(s)
Principal Investigator

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
320652

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NIHR204036, IRAS 320652, CPMS 56928

Study information

Scientific Title
Paediatric Otorrhoea Study (POSt): Understanding the burden of disease and acceptability of non-surgical management options

Acronym
POSt

Study objectives
The primary objective of this study is to improve the understanding of the impact of paediatric otorrhoea (PO) on children and young people (CYP) and their carers.

The secondary objectives of this study are to understand how and why CYP with PO are currently treated and to assess treatment and randomisation acceptability for CYP, their parents/carers and healthcare professionals for a future RCT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design

Qualitative Research - Semi-structured patient interviews & medication professional focus groups

Primary study design
Observational

Secondary study design
Qualitative study

Study setting(s)
Home, Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Otorrhoea

Interventions
Patients will undertake a 60 minute semi structured interview with a qualitative researcher. Medical professionals will take part in a 60 minute focus group using a semi structured format. No subsequent follow up after the interview or focus group will be organised. Participants will be offered to be informed of the study findings. Total duration of involvement in the study is 1 day.

Intervention Type
Other

Primary outcome measure
Patient Interview Objectives:
Understand the patient and carer experience of the condition using a 60 minute semi structured interview with a qualitative researcher analysed using thematic analysis

Medical Professional Focus Group Objectives:
Explore the experiences of medical professionals who manage children and young people with paediatric otorrhoea using a 60 minute focus group using a semi structured format analysed using thematic analysis

Secondary outcome measures
Patient Interview Objectives:
Using a 60 minute semi structured interview with a qualitative researcher analysed using thematic analysis:
1. Understand the patient and carer experience of treatment
2. Identifying in the patient and carer’s opinion how they define treatment success
3. Identifying in the patient and carer’s opinion on randomisation in a future trial

4. Identifying in the patient and carer’s opinion on taking placebo medications
5. Identifying in the patient and carer’s opinion on motivators and barriers to participating in a randomised controlled trial

Medical Professional Focus Group Objectives:
Using a 60 minute focus group using a semi structured format analysed using thematic analysis
1. Understand the medical professional’s normal treatment practice
2. Understand how medical professional’s define treatment success
3. Understand the medical professional’s motivations and barriers to participating in a future randomised controlled trial

Overall study start date
01/11/2022

Completion date
31/03/2024

Eligibility

Key inclusion criteria
Children and young people aged 16 years and under who have or have had otorrhoea in the past 1 year & medical professionals who interact with this patient cohort

Participant type(s)
Patient, Health professional, Service user

Age group
Child

Lower age limit
0 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
30 patients and 24 medical professionals

Key exclusion criteria
Not experienced otorrhoea in the preceding year

Date of first enrolment
19/06/2023

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Manchester Children's Hospital (Manchester University NHS Foundation Trust)
Oxford Road
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Manchester University NHS Foundation Trust

Sponsor details
Research Office
1st Floor, Nowgen Building
29 Grafton Street
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M13 9WU
+44 7815987923
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Sponsor type
Hospital/treatment centre

Website
https://mft.nhs.uk/

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The research findings will be presented at medical conferences and submitted for publication in one or more peer reviewed journals. In addition, we will publish the research on social media and the sponsor's webpage to highlight the research findings.

We will work with our PAG members, public members involved in the study workshop, and the Dipex charity to formulate an engagement plan to ensure the research findings are heard by the relevant audience. We will develop online materials with the Dipex charity for their website https://healthtalk.org which includes over 100 health topics.

We aim to empower PAG members to help disseminate the research outcomes via local networks and online forums. We do not believe there are any potential risks or sensitivities for research dissemination in this area.

Intention to publish date
01/06/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		05/09/2023	06/09/2023	Yes	No
Results article		21/10/2024	03/04/2025	Yes	No