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BioEvocs - Testing the 'poo sniffer' in children and young people with eosinophilic esophagitis

Submission date
16/10/2023

Recruitment status
Recruiting

Registration date
20/12/2023

Overall study status
Ongoing

Last Edited
05/02/2025

Condition category
Digestive System

[ ] 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
Many children and young people coming to our clinics have problems with their tummy (gastrointestinal system). We do special tests to find out what their illness is so that we know what treatment they need. An important illness that we see is eosinophilic oesophagitis (EoE). This is when the lining of the gullet becomes sore (inflamed) leading to problems of swallowing, food stuck in the gullet and ongoing gastro-oesophageal reflux. At present, we need to perform one or many camera tests repeated (endoscopy) for this illness when children are fully asleep (under general anaesthetic).
Endoscopy is when we look inside the tummy with a camera. It is done under general anaesthetic so that the patient doesn't feel anything.
So far for EoE no bedside test (biomarker) exists to tell us if the gullet and tummy are inflamed for any reason. That means we have to repeat an endoscopy every time when a change in treatment (medicine or diet) is needed for EoE. We want to see if doing a simple stool sample helps more to inform us if treatment with medicines or diet is working.
The new test measures the many different gases (volatiles) that give stool its smell. The volatiles come from the contents and lining of the bowel and are affected directly or indirectly by gut bacteria in the stool and we can measure them in the lab with special instruments. Volatiles will also be affected by the nutrition and metabolism of nutrition/nutritional compounds. Some illnesses change the volatiles and we want to see if measuring them gives us an extra way of finding out about active EoE. If successful, this may mean we do not need so many endoscopies. Also, the new test may allow us to tell if medicines or diet change gut bacteria in a positive, healthier way. We also want to see if measuring the volatiles again in young people who turn out to have EoE is a good way of monitoring whether their treatment is working. Finally, measuring the volatiles in stool may tell us more about what causes EoE and gullet (oesophageal) disease.

Who can participate?
Patients with eosinophilic esophagitis (EoE) and patients coming to participating hospitals either with problems of their gullet (oesophageal controls) or patients without tummy problems who come to the eye clinics (ophthalmology patients).

What does the study involve?
Participants are requested to bring in (donate) a stool sample.

What are the possible benefits and risks of participating?
The new test on the poo sample will be done at the end of the study with all the other stool samples. The result of the new test will not be used in the diagnosis or monitoring of illness. However, it is hoped that the new test will help children and younger people in the future. The researchers do not think that this study will cause any problems.

Where is the study run from?
The study is so far being run in one children's hospital (Alder Hey Children's Hospital) but will be extended to four other children's hospitals (Great Ormond Street and Chelsea and Westminster in London and in Sheffield and Newcastle).

When is the study starting and how long is it expected to run for?
June 2019 to October 2025

Who is funding the study?
1. National Institute for Health and Care Research (UK)
2. Guts UK
3. British Society for Paediatric Gastroenterology (BSPGHAN) (UK)

Who is the main contact?
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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
320020

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 320020, CPMS 56128

Study information

Scientific Title
BioEvocs - Faecal volatile organic compounds in children with eosinophilic oesophagitis: potential as non-invasive biomarkers

Study objectives
The hypothesis is that patients with eosinophilic oesophagitis (EoE) have a gut microbiome associated with a specific volatile organic compound (VOC) signature, which can then be used to monitor and treatment stratify the disease in a manner that will allow advising on medical or dietetic induction and need for maintenance treatment. VOC assessment may also help to better understand the role of nutrition in association with oesophageal (EoE and other) diseases.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/02/2023, North West - Haydock Research Ethics Committee (3rd Floor - Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 (0)2071048032; haydock.rec@hra.nhs.uk), ref: 22/NW/0341

Study design
Observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic, Screening

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
Eosinophilic esophagitis

Interventions
This will be a case-control feasibility study that collects faecal samples from patients undergoing diagnostic assessment or treatment for EoE, and from normal controls and controls of patients with oesophageal disease without EoE. The researchers will collect faecal samples and clinical /demographic as well as nutritional and atopy data. Clinical activity scores validated for paediatric EoE (PEESS v 2.0) will be investigated. The study will last 2 years followed by data analysis and preparation of manuscripts. The researchers aim to collect samples and data from 60 patients with EoE (before and after change of treatment) and 60 controls without EoE (180 samples in total).

Intervention Type
Other

Primary outcome measure
Patterns of volatile organic compounds associated with active EoE, measured using gas chromatography-mass spectrometry at baseline and 3 months

Secondary outcome measures
1. Patterns of volatile organic compounds treated with medical (oral viscous budesonide) or dietetic (elimination diet) treatment, measured using gas chromatography-mass spectrometry at baseline and 3 months
2. Patient disease activity measured using Pediatric Eosinophilic Esophagitis Symptom Score (PEESS) score at baseline and 3 months
3. Nutritional status and atopic background measured using Environmental questionnaire at

baseline
4. Microbiome selected analysis and CGR (Centre for Genomic Research) sequencing of fecal sample at baseline and 3 months

Overall study start date
17/06/2019

Completion date
31/10/2025

Eligibility

Key inclusion criteria
For EoE:
Children attending endoscopy or clinic for known EoE or to investigate symptoms indicating flare-up of disease symptoms contacting the department, or patients found to have EoE who are awaiting treatment.

For controls:
Control patients identified in gastroenterology or ophthalmology outpatient clinics

Participant type(s)
Healthy volunteer, Patient

Age group
Child

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Patients unable to provide a faecal sample
2. Patients and parents unable to give informed consent
3. Previous colonic resection
4. Patients on an elemental diet unrelated to EoE
5. Current or treatment with systemic antibiotics in the previous 4 weeks
6. Patients with known chronic gastro-intestinal infection or chronic diarrhoea
7. Patients with confirmed and clinically significant irritable bowel syndrome

Date of first enrolment
24/10/2023

Date of final enrolment
30/08/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Alderhey
Eaton Road
West Derby
Liverpool
United Kingdom
L12 2AP

Study participating centre
Great Ormond Street Hospital Central London Site
Great Ormond Street
London
United Kingdom
WC1N 3JH

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Sheffield Childrens Hospital
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
The Royal Victoria Infirmary and Associated Hospitals NHS Trust
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Alder Hey Children's Hospital

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Sponsor type
Hospital/treatment centre

Website
http://www.alderhey.nhs.uk/

ROR
https://ror.org/04z61sd03

Funder(s)

Funder type
Government

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

Funder Name
Guts UK

Funder Name
British Society for Paediatric Gastroenterology

Results and Publications

Publication and dissemination plan
1. Publication in peer-reviewed journal
2. Presentation at conference

Intention to publish date
01/03/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.
The name of the repository: BioEvocs CRF spreadsheet.
The type of data stored: dichotomous and continuous data from questionnaires. BioEVOCS CRF files. Password-protected Excel sheets on the hospital computer drive.
The process for requesting access (if non-publicly available): contact research@alderhey.nhs.uk.
Dates of availability: after data analysis and publication (not before March 2026).
Whether consent from participants was required and obtained: required and will be obtained before recruitment.
Comments on data anonymization: pseudo-anonymous: letters for site, condition, baseline or follow-up, followed by three-digit running site number.

IPD sharing plan summary
Stored in non-publicly available repository