

Faecal volatiles in children with inflammatory bowel disease

Submission date 08/05/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 31/07/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/08/2023	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Inflammatory bowel disease (IBD) is a term used to describe conditions which cause long-term inflammation (swelling) in the gut. The two main forms of IBD are Crohn's disease (CD) and ulcerative colitis (UC). Crohn's disease can affect any part of the gut, but is most commonly at the end of the ileum (the last part of the small intestine) or the colon (the large intestine). Ulcerative colitis generally affects the colon and rectum (the last part of the large intestine). It has become much more common in children in recent years such that 1 in 4 of all new cases now occur in young people. Gastrointestinal endoscopy (a test where a flexible tube with a camera on the end is through the mouth into the gut) and imaging are required to confirm a diagnosis in children with suspected IBD. These investigations can be distressing for some children and their families, can delay diagnosis and the start of treatment and are costly to the NHS. They also often need repeating at regular intervals further impairing quality of life. Children and families voice a strong desire for tests that are non-invasive and give a rapid result. The measurement of a marker called "calprotectin" in a stool sample is very helpful in detecting intestinal inflammation. However, it does not distinguish IBD from other causes of intestinal inflammation such as gut infections. Various human tissues, including stool, give off vapours that contain volatile organic compounds (VOCs) that give them their characteristic smell. VOCs are produced by the cells lining the intestine and the microorganisms in the gut and can be measured quickly in the clinic at low cost. The type and quantity of VOCs change when the intestine is affected by a disease. It has been shown that the VOCs in adults with IBS were different from those with IBD. Also, VOCs were different in adults with inflammation of the large bowel due to Crohn's disease than due to ulcerative colitis. The aim of this study is to see whether stool VOCs can replace other investigations for IBD such as endoscopy and imaging in children.

Who can participate?

Children who have suspected IPD who have been referred to gastroenterology clinics for investigation.

What does the study involve?

Information about age, symptoms and factors that could change children's gut bacteria such as recent treatment with antibiotics is collected before children are assessed investigated by their usual doctors in the usual way. Three months later, medical records are reviewed to find out

what diagnosis was made. Stool VOCs that were present when they first came to hospital in those who turn-out to have IBD with those who have other gastrointestinal problems are then compared. In children who turn-out to have IBD, the researchers also see if the stool VOCs differed according to the type of disease (Crohn's disease versus ulcerative colitis), how severe the inflammation was and the part of the intestine affected. Finally, measure stool VOCs are measured again at three months in children with IBD to see if it a useful way of assessing their response to treatment.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved for participants.

Where is the study run from?

1. Alder Hey Children's Hospital (UK)
2. Bristol Royal Hospital for Children (UK)
3. Birmingham Children's Hospital (UK)

When is the study starting and how long is it expected to run for?
June 2017 to April 2019

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

Who is the main contact?
Professor Stephen Allen
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

PB-PG-1215-20050

Study information

Scientific Title

Evaluation of faecal volatile organic compounds in the diagnosis of paediatric inflammatory bowel disease

Study objectives

Principal research questions:

1. Does the measurement of faecal volatile organic compounds (VOCs) distinguish children presenting with inflammatory bowel disease (IBD) from those presenting with other common gastrointestinal disorders?
2. Does the measurement of faecal VOCs in children treated for IBD distinguish those in clinical remission from those with persistent disease?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 12/06/2017, North West - Preston Research Ethics Committee (address not provided; +44 (0)2071048290; reston.rec@hra.nhs.uk), ref: 17/NW/0333

Study design

Prospective observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format; please use contact details to request patient information sheets

Health condition(s) or problem(s) studied

Inflammatory bowel disease and common gastrointestinal disorders in children referred for specialist paediatric gastroenterology review

Interventions

Potential participants will be identified by their clinical team by reviewing referrals to out-patient clinics, children attending for ward review or referred directly for investigations such as endoscopy. Children will be asked to collect a stool sample to bring to the hospital. Stool samples will be used for the measurement of calprotectin for the assessment of intestinal inflammation as part of routine clinical practice. Following informed consent, an aliquot of the stool sample will be stored for the measurement of VOCs at the end of the study. Faecal VOCs will be measured by two methods: i) headspace SPME-Combipal GCMS and ii) the GC-sensor "Odoreader®".

The clinical team will undertake investigations as appropriate to determine the diagnosis /diagnoses. The clinical records of all children will be reviewed 3 months after recruitment to record the results of investigations and diagnoses. In children who are diagnosed with inflammatory bowel disease, the follow-up at 3 months will also assess disease activity and record the treatment that they have received.

Intervention Type

Other

Primary outcome measure

Faecal VOCs at initial presentation to paediatric gastroenterology measured by headspace SPME-Combipal GCMS and the GC-sensor Odoreader® at initial presentation.

Secondary outcome measures

1. Faecal VOCs at initial presentation in children with IBD according to IBD diagnosis, distribution and disease severity
2. Faecal VOCs at 3 months after the initial presentation in children with inflammatory bowel disease according to disease activity
3. Likely source of the faecal VOCs identified by GCMS at initial presentation determined by existing KEGG databases (<http://www.genome.jp/kegg/kegg2.html>)

Overall study start date

27/06/2017

Completion date

30/06/2020

Eligibility

Key inclusion criteria

1. Children (age <18 years) capable of giving informed consent, or if age < 16 years or not capable of giving consent, with an acceptable individual capable of giving consent on the child's behalf
2. Children of either gender attending a paediatric gastroenterology referral clinic in whom IBD is suspected following initial clinical assessment
3. Further evaluation planned to diagnose the cause of the child's illness
4. Willing for demographic and clinical information to be used for the purposes of the study
5. Willing for part of the stool sample provided for routine clinical assessment to be used for the measurement of VOCs

Participant type(s)

Patient

Age group

Child

Upper age limit

18 Years

Sex

Both

Target number of participants

286

Total final enrolment

264

Key exclusion criteria

1. Treatment already received for IBD (e.g. polymeric formula feeds in children awaiting investigation)
2. Established diagnosis of a significant gut disorder (e.g. short bowel syndrome)
3. Failure to obtain informed consent from the young person or parent/guardian

Date of first enrolment

27/06/2017

Date of final enrolment

30/06/2020

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Alder Hey Children's Hospital

Eaton Road

Liverpool

United Kingdom

L12 2AP

Study participating centre

Bristol Royal Hospital for Children

Paul O'Gorman Building

Upper Maudlin Street

Bristol
United Kingdom
BS2 8BJ

Study participating centre
Birmingham Children's Hospital
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Sponsor information

Organisation
Alder Hey Children's NHS Foundation Trust

Sponsor details
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Liverpool
England
United Kingdom
L12 2AP
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Sponsor type
Hospital/treatment centre

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

ROR
<https://ror.org/00p18zw56>

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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

Publication and dissemination plan

The study findings will be of interest to clinicians, allied health professionals and researchers working in IBD and also those interested in the measurement of VOCs in the diagnosis and management of a wide range of diseases. Planned publication the study protocol and share our findings at specialist society meetings and key scientific conferences.

Intention to publish date

15/02/2024

Individual participant data (IPD) sharing plan

The study database will be publicly accessible through a central data management system at the Liverpool School of Tropical Medicine or available on request. Dissemination of results to clinicians, allied health professionals and academics will be facilitated by membership of the investigators on specialist society groups and charity boards. Planned use of these channels to encourage further research to explore the utility of VOCs in paediatric IBD and in clinical practice more broadly.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2.0	11/10/2017	28/09/2022	No	No
HRA research summary			28/06/2023	No	No