Participant Information Sheet

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Title of Study: CHARACTERISING THE EFFECTS OF RELIEVING STRICTURE OBSTRUCTION BY ILEOCOLONIC STENTING - A PILOT STUDY INTO MOTILITY, MICROBIOMICS & METABOLOMICS IN CROHN'S DISEASE

(The Crohn's Stricture CS3M Study - CS3M)

IRAS Project ID: 252808

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Name of Researchers: Dr. Andrew Cole, Mr. Jon Lund, Dr. Ronit Das

Welcome to the 'Crohn's Stricture CS3M Study', or as we will now refer to it as in short, the 'CS3M Study'. We would like to invite you to take part in our research study. You have been recommended to have a stent to treat a Crohn's Disease stricture. The intention of this study is to measure how the gut's bacteria, bacterial products and movement changes as a result of stenting.

There has been careful review of your condition. Your tests and scans have been reviewed in an expert meeting. A narrowing has been seen within your bowel and is likely causing you difficulty. The clinical treatment proposed is a process called 'stenting'. Prior to, and following a 'stent' being placed within your bowel we would like to conduct scans and collect samples. What is required for participation in the study and further details are now presented.

Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

1. What is the purpose of the study?

The 'CS3M Study' hopes to identify particular changes related to the placement of a stent within the bowel and the resolution of identified 'strictures'. In short we will measure the effects of stenting on how the bowel contracts, how the gut's bacteria changes, and how bacterial products change.

The study is a 'pilot study'. This means that techniques, methods and overall study design are being assessed prior to a full-scale study.

2. Why have I been invited?

You have been invited because you have been diagnosed with Crohn's disease and also have narrowing of the bowel, called a 'stricture'. The identified stricture is also appropriate for stent therapy. We are inviting 14 participants like you to take part in the study.

3. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. Taking part in the study is your choice. You are free to be involved and equally free to withdraw from the study at any time. Withdrawing from the study will not negatively affect your ongoing or future treatment in any way. Withdrawing from the study will not affect your legal rights in any way.

4. What will happen to me if I take part?

Your planned clinical treatment is the is the placement of a stent within a narrowing in the bowel. The stent is placed during a 'colonoscopy' and then removed with a further 'colonoscopy'. You will have two separate MRI scans, one of which is purely research oriented. In addition to this you will be asked to give a total of three stool samples. The scans and samples collected will be key elements of the study.

5. What will I have to do?

The activities can be thought of as six separate hospital attendances, only one of which is in addition to normal clinical care (Visit 5):

- Attendance #1: Initial Clinic Visit
- Attendance #2: MRI Scan

- Attendance #3: Colonoscopy & Stent Insertion
- Attendance #4: Colonoscopy & Stent Removal
- Attendance #5: MRI Scan (Research visit)
- Attendance #6: Clinic Review

There will be further instructions given to you regarding each attendance. The study activities for you will last between 6 to 8 weeks. You will be contacted 6 months following the study to see how you are, via telephone.

6. Will my routine clinical care be affected?

Your care will not be negatively affected in any situation. Your involvement in the CS3M study is entirely voluntary.

7. How many visits to Hospital will be needed for research purposes?

Only a single visit (the 2nd MRI Scan at Royal Derby Hospital – Radiology Department) is for purely research purposes. All other stool sample collection and other activities will occur within your 'routine clinical care'.

8. Will I receive any payment for my involvement in the study?

Involvement in the study is not paid. However a single inconvenience allowance of £50 will be made to compensate participants. Parking costs will be reimbursed by the Endoscopy Department for the single research only visit.

9. What are the possible disadvantages and risks of taking part?

It is unclear if stenting a bowel narrowing in Crohn's disease is the ideal method of treatment. Procedural risks will be explained to you at your clinic appointment. MRI scans themselves do not pose any known health risks.

10. What are the possible benefits of taking part?

The information gathered will give a detailed understanding of your condition and symptoms. Throughout the study period you will have rapid access to Inflammatory Bowel Disease specialists. Information from this study may go on to help Crohn's disease patients throughout the world.

11. **Is any part of the treatment experimental?**

No - Colonic stenting is a routine procedure. Data from your scans and stool samples is what gives us a new insight.

12.What happens when the research study stops?

Your Crohn's disease care will continue with your original consultant & team. Your questions or any other queries should be directed via the identified helpline. Once all the data collected in the study is analysed and appropriately assessed, you will be contacted with results. If a further large scale study is planned based on pilot data, all CS3M study participants will be informed.

13.What if there is a problem?

You are encouraged to discuss any issues openly with the research team. If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet.

If you remain unhappy and wish to complain formally, you can do this by contacting Royal Derby Hospital Patient Liaison Service (PALS – dhft.contactpals@nhs.net / 07799337500 / 01332785156 / 08007837691).

In the event that something does go wrong and you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

14.Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence. EU & UK data protection regulations are adhered to as part of study practice and research policy. If you join the study, we will use information collected from you [and your medical records] during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data).

This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at: https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Where possible information about you which leaves the hospital will have your name and address removed and a unique code will be used so that you cannot be recognised from it, however sometimes we need to ensure that we can recognise you to link the research data with your medical records so in these instances we will need to know your name and date of birth. By signing the consent form you agree to the above.

Your contact information will be kept by the University of Nottingham for 12 months after the end of the study so that we are able to contact you about the findings of the (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other research data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

All your personal information will kept confidential. All research information will be kept safely during and following the study. Information will be stored in locked and electronically secure locations. Results from the study will go on to generate scientific publications only. Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

15. What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. Leaving the study will not affect the standard of current or future medical care you receive.

If you withdraw we will no longer collect any information about you or from you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible.

16. **Will my GP know that I am involved in this study?**

With your consent, your GP will be notified of your involvement and the nature of the study. It is not necessary for your GP to be aware of your involvement in the study.

17. What will happen to any samples I give?

Your stool samples should be given to the Research Fellow (Dr. Ronit Das – Royal Derby Hospital). The stool samples you provide will be analysed for bacterial content and other markers. Each stool sample will always be securely stored. The handling and usage of samples is legally covered under the 'Human Tissue Act' of 2004. Stool analysis will occur at other sites outside of the University of Nottingham and the Royal Derby Hospital. The University of Liverpool and the Centre for Genomic Research will be the external sites.

We would also like to seek your consent so that any remaining stool samples may be stored and used in possible future research – this is optional (please indicate you agree to this on the consent form). The samples will be stored with a code unique to you and securely at the University of Nottingham under the University's Human Tissue Research Licence (No. 12265).

Some of these future studies may be carried out by researchers other than current team, including researchers working for commercial companies. Any samples or data used will be anonymised, and you will not be identified in anyway. If you do not agree to this any remaining samples will be disposed of in accordance with the Human Tissue Authority's codes of practice.

18.What will happen to the results of the research study?

The information produced by the study will be analysed. Observations will go on to be submitted for scientific publication. We will contact you with finalised study results. Study results will additionally contribute towards the award of a research degree - PhD or as appropriate.

19.Who is organising and funding the research?

This research is being organised by the University of Nottingham. Funding is currently being provided by a Gastroenterology Departmental Research Fund and the Royal Derby Hospital Charitable Fund. Further funders may be sought in the future.

20.Who has reviewed the study?

All research in healthcare is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by a Research Ethics Committee.

21. **How can I know more about the study & what is involved?**

Further information can be provided to you. In the following pages you will find the contact information of the research team. The first person to contact with queries is Dr. Ronit Das (IBD Research Fellow).

Further information and contact details

IBD Research Fellow - Dr. Ronit Das

Tel: 01332 340131 x86004 or Via Switchboard

Address: Royal Derby Hospital, Derby, Derbyshire, DE22 3NE
Website: http://www.derbyhospitals.nhs.uk
Email: ronit.das@nhs.net

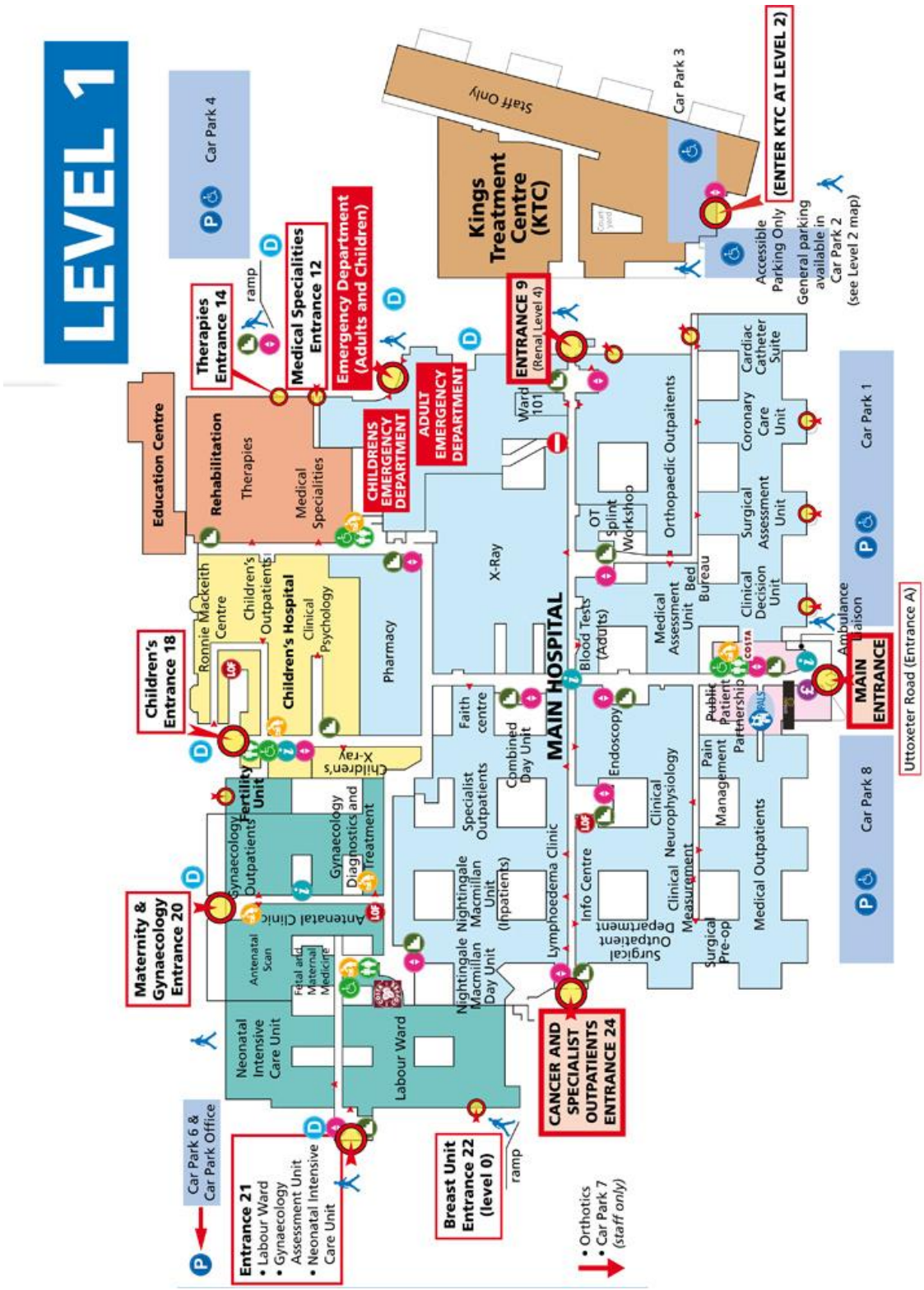
IBD Nursing Hotline

Tel: 01332 340131 x785504

Address: Royal Derby Hospital, Derby, Derbyshire, DE22 3NE
Website: http://www.derbyhospitals.nhs.uk
Email: dhft.ibdadvice@nhs.net

Royal Derby Hospital

Tel: 01332 340131 Fax: 01332 785566
Address: Royal Derby Hospital, Derby, Derbyshire, DE22 3NE
Website: http://www.derbyhospitals.nhs.uk
Email: dhft.contactpals@nhs.net


LEVEL 1
Car Park 4
Staff Only
Car Park 3
Kings Treatment Centre (KTC)
(ENTER KTC AT LEVEL 2)
Accessible Parking Only
General parking available in Car Park 2 (see Level 2 map)
Therapies Entrance 14
ramp
Medical Specialities Entrance 12
Emergency Department (Adults and Children)
ENTRANCE 9 (Renal Level 4)
Education Centre
Rehabilitation Therapies
Medical Specialities
CHILDRENS EMERGENCY DEPARTMENT
ADULT EMERGENCY DEPARTMENT
Ward 101
Cardiac Catheter Suite
Coronary Care Unit
Surgical Assessment Unit
Car Park 1
Orthopaedic Outpaitents
OT Splint Workshop
X-Ray
Clinical Decision Unit
Ambulance Liaison
Ronnie Mackeith Centre
Children's Outpatients
Children's Hospital
Clinical Psychology
Pharmacy
Medical Assessment Unit
Bed Bureau
Blood Tests (Adults)
MAIN HOSPITAL
MAIN ENTRANCE
Uttoxeter Road (Entrance A)
Children's Entrance 18
Children's X-ray
Faith centre
Combined Day Unit
Specialist Outpatients
Endoscopy
Public Patient Partnership
Pain Management
Clinical Neurophysiology
Fertility Unit
Gynaecology Outpatients
Gynaecology Diagnostics and Treatment
Antenatal Clinic
Nightingale Macmillan Unit (Inpatients)
Info Centre
Lymphoedema Clinic
Clinical Measurement
Medical Outpatients
Car Park 8
Maternity & Gynaecology Entrance 20
Antenatal Scan
Fetal and Maternal Medicine
Nightingale Macmillan Day Unit
Surgical Outpatient Department
Surgical Pre-op
Neonatal Intensive Care Unit
Labour Ward
CANCER AND SPECIALIST OUTPATIENTS ENTRANCE 24
Car Park 6 & Car Park Office
Entrance 21
• Labour Ward
• Gynaecology Assessment Unit
• Neonatal Intensive Care Unit
Breast Unit Entrance 22 (level 0)
ramp
• Orthotics
• Car Park 7 (staff only)

Site Research Team

Principal Investigator

Dr. Andrew Cole
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Chief Investigator

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