



Optimisation before Crohn's surgery using Exclusive Enteral Nutrition (OCEaN) Sub-Study:

Crohns Optimisation And Surgical Timing (COAST)

Participant Information Sheet

Version 2.0 19-NOV-2024

We would like to invite you to take part in the COAST study

You have been invited to take part in this study because you are involved in the OCEaN research study. Before you decide whether to take part or not, you need to understand what COAST is about, and what it would involve for you. Taking part in research is entirely voluntary; it is up to you to decide whether you would like to take part in COAST or not. If you do decide to take part in COAST, you are free to withdraw at any time and do not have to give any reason for your decision. Nobody will be upset, and the standard of care you receive will not be affected if you decide not to take part. You can also continue to take part in the main OCEaN research study without taking part in COAST.

Please take time to read the following information carefully. **One of our team will go through the information sheet with you, explain the sub-study in more detail, and answer any questions you have.** If anything is not clear or you would like more information, do not hesitate to ask a member of the local research team (see contact details at the end of this information sheet). Talk to others about the study if you wish, such as friends or relatives, and take time to decide. If you decide to take part you will be asked to complete an ethically approved consent form.

What is the purpose of the COAST study?

COAST is an additional study which asks questions about your food intake and the psychosocial aspects of eating (food-related quality of life) before and after your operation.

The COAST study will help us identify if your diet and food-related quality of life has changed since your Crohn's operation, and whether a special liquid diet has been helpful.

Why have I been invited to take part in COAST?

You have been invited to take part in COAST because you are taking part in the OCEaN research study.

What will happen to me if I take part?

If you do decide to take part, the local research team will ask for your consent and you will be given this information sheet and a copy of the consent form. Your consent form will stay on record in the study file and your medical records and be available for review by the trial monitors. With your permission, a copy of your signed consent form will also be sent to the OCEaN Study Office at the University of Birmingham. You will be asked to complete two questionnaires at baseline, and at 6 weeks and 12 months after your operation.

- **Food frequency questionnaire (FFQ)** – this questionnaire will ask you how often you eat different types of food and in what quantities. It should take 20-25 minutes to complete.
- **Food related quality of life in IBD (FRQOL)** – this questionnaire will measure the psychosocial aspects of eating. It should take 5 minutes to complete.

Do I have to take part?

No, the decision to take part in this study is entirely your own choice. It is up to you to decide whether or not you would like to take part in the COAST study. If you decide not to, it will not affect the care you receive in any way and you can still continue taking part in the OCEaN study.

What are the possible disadvantages of taking part?

The questionnaires will give us information on your diet and experience in relation to surgery so is very unlikely to be disadvantageous for you. If you feel that the study is causing undue distress or emotional discomfort, you can end it at any time.

What are the possible benefits of taking part?

We cannot promise that taking part in the COAST study will benefit you directly. However, it will help us understand the role of diet and the timing of surgery in Crohn's disease.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your initials / name/ contact details by the Sponsor for the research. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Should you opt in to SMS communication, your mobile number will be shared with a UK-based, GDPR compliant third-party SMS platform to send you text messages for completing the questionnaires. Your data will not be used by the third-party for any other purpose.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- In the leaflet available from www.hra.nhs.uk/patientdataandresearch
- By asking one of the research team
- By sending an email to dataprotection@contacts.bham.ac.uk, or

What if there is a problem?

We do not envisage any problems as a result of your participation in the trial. If you have any concerns or questions about any aspect of this study, please contact the research team (details can be found at the end of this information sheet) who will do their best to answer your questions. Please feel free to ask any further questions before deciding to take part in the interviews.

If you remain unhappy and wish to complain formally, you can do this through the normal National Health Service complaints mechanisms, this is usually the Patient Advisory and Liaison Service (PALS) or your hospital complaints service. The contact details can be found on the end of this Patient Information Sheet or via this website:

<https://www.nhs.uk/common-health-questions/nhs-services-and-treatments/what-is-pals-patient-advice-and-liaison-service/>

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

You can withdraw from the study at any time and without giving a reason. A decision to withdraw at any time or a decision to not take part will not affect the standard of care you receive. You can also continue taking part in the main OCEaN research study. If you withdraw, we will not collect any further data, but any information collected before your withdrawal will be kept and used for the research.

What will happen to the results from the COAST study?

The findings of the study will be made public. We will write reports on the results of this study and make them suitable for the general public. Our patient group will help us write reports and share on social media as well as patient support groups such as Crohn's & Colitis UK. All findings will also be written as a formal research report and will be published in a freely accessible journal. No individual participants will be identifiable in any report or publication.

Who is organising and funding the research?

COAST is funded by Crohn's and Colitis UK, and is being organised by the Birmingham Clinical Trials Unit based at University of Birmingham. The University of Birmingham is the Sponsor for the OCEaN study.

No member of the research team is being paid for including you in this study.

Who has looked at the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favourable opinion by the Seasonal Research Ethics Committee.

Any questions and what next?

Thank you for taking the time to read this information sheet and for considering taking part in COAST.

If you are interested in talking to a researcher about your experiences or have any questions regarding this study please do not hesitate to contact the local research team (see details below).

If you have any questions, please contact the local study research team on

Name:	
Job Title:	
Contact Details:	

Alternatively you can contact the COAST study office:

COAST Research Office
4.104 Franklin Wilkins Building
150 Stamford Street
King's College London
SE1 9NH
Email: coast@kcl.ac.uk

Or the OCEaN study Office:

OCEaN Trial Office
Birmingham Clinical Trials Unit (BCTU)
Public Health Building
University of Birmingham
B15 2TT
Email: ocean@trials.bham.ac.uk

The research is being funded by Crohn's and Colitis UK (project reference M2022-5 Lomer).