PROPHER PATIENT IDENTIFICATION NUMBER

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PROPHER: Patient Reported Outcomes after Parastomal HErnia tReatment

A prospective international cohort study

PATIENT INFORMATION SHEET

Version 5.0, [21st June 2023]

We would like to invite you to take part in the **PROPHER** research study. Joining the study is completely voluntary. Before you decide, we would like you to understand why the research is being done and what it would involve for you. A member of the local research team will go through this information sheet with you, to help you decide whether or not you would like to take part and to answer any questions you may have.

Part 1 of this Participant Information Sheet (PIS) tells you the purpose of the study. Part 2 gives more detailed information about what will happen to you if you take part and about the conduct of the study. Please do take the opportunity to talk to others about the study if you wish, and to ask any questions you might have if anything is unclear.

Part 1

What is the purpose of the PROPHER study?

PROPHER stands for Patient Reported Outcomes after Parastomal Hernia Treatment. The overall aim is to see what the impact on the patient's quality of life is from having treatment for a parastomal hernia. The study will also look at how parastomal hernias are treated, for example having an operation and any complications that happen in the first 30 days, or deciding to "watch and wait". It will also look at whether there are any links between the way that a surgeon repairs a parastomal hernia and the outcomes.

What is a parastomal hernia?

Stoma formation is often necessary after bowel surgery. A common complication of a stoma is a parastomal hernia (PSH) - caused by a weakness in the abdominal muscle which results in a local bulge next to or behind the stoma. A PSH can cause skin irritation, problems with getting a stoma bag to stick, as well as pain and other more serious complications such as bowel obstruction. These issues often have a negative impact on a patient's quality of life

What are patient reported outcomes?

Patient reported outcomes (PROMS) are questionnaires that measure the patient's view of their own health. Questionnaires are completed before and after treatment so that health care professionals and researchers can see how the treatment has impacted on the patient.

Who is organising and funding the research?

PROPHER was developed by a group on behalf of the European Society of Coloproctology (ESCP) and has been funded by the Bowel Research UK and ESCP. The study is being coordinated by the ESCP team based at the University of Birmingham, UK.

What are the possible benefits of taking part in PROPHER?

While there is no direct benefit to you in taking part in **PROPHER**, you will be helping us to help future patients with parastomal hernias.

How have patients and the public been involved in this study?

Patients have given us their feedback on the questionnaires we are using in the study, and how we are collecting the information. Potential participants were involved in reviewing the Participant Information Sheet.

Part 2

Why have I been chosen?

Your surgeon or stoma care nurse is involved in the **PROPHER** study as they feel that the study is important. As such they are inviting all their patients that they speak to about treatment for their parastomal hernia to take part in the study. **PROPHER** will include patients with a parastomal hernia from hospitals across the UK, Europe and the rest of the world

Who is eligible to take part in PROPHER?

Anyone who is 18 or over, who has a parastomal hernia around their ileostomy or colostomy is eligible to take part in PROPHER. Eligible patients are those who are planning on having an operation to repair their parastomal hernia, as well as those who have opted for conservative (non-operative) management.

People who have a parastomal hernia around a urostomy, or those who have less than 12 months to live are not eligible to take part in PROPHER.

What would taking part in PROPHER involve?

If you agree to take part in the study you will be asked to complete questionnaires regarding your parastomal hernia as well as information about how you are feeling at various stages throughout your treatment. These details about you will be collected at the start (baseline), at three months, six months and at 12 months. The local study investigator(s) will also record some additional information about your medical history, and if you have an operation as part of your treatment, they will record details about your operation

How will you collect the information from me?

If you wish to participate in this study, you will be provided with a unique PROPHER identification number by your surgeon or stoma care nurse (the local investigator for the PROPHER study). You will only ever be identified by the unique PROPHER identification number which has been assigned to you.

Once you have been provided with the identification number, you will then be asked to access the PROPHER patient website. On the website, you will be asked to log in securely and give your consent to answer questions about your health, this will be done via a secure UK based online

database system called REDCap, which is hosted by the University of Birmingham. We will need to collect your email address and mobile phone number so that we can send you a link to your questionnaires. This information will be kept secure on the University of Birmingham system and only the study administrators will be able to access this.

The questionnaires you will need to complete will then be sent to you via email. You can answer the questionnaires using the web browser on your phone or on a computer.

How long will the PROPHER study last?

PROPHER will start in 2023 and we plan to recruit patients for 24 months. Participation will be for 12 months for both operative and non-operative patients. However, if you are a non-operative patient who goes onto have surgery, we will ask that you complete questionnaires for a further 12 months from your surgery date. At the end of the patient follow up questionnaires at 12 months, we may ask you if you would be prepared to continue to complete questionnaires for a further 12 months, but this is voluntary and is dependent on further funding.

Do I have to take part?

No. Taking part in research is always voluntary. If you decide to take part you will be asked to sign a consent form but you are still free to withdraw at any time and without giving a reason. If you decide not to take part, you don't have to give any reason why and no-one will think badly of you for not wishing to take part. Your care will not be affected in any way. Your surgeon, stoma care nurse, or local study investigator will be happy to talk you through any questions you may have regarding **PROPHER**.

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

You can decide not to continue with study follow-up at any time but, if you do, we will keep the information about you that we already have and it will be included in the study analysis

How we will use information about you

We will need to use information from you, and from your medical records for this research project, and some of this data will be used in a PhD study. This information will not include any identifiable data. You will be assigned a unique study ID when you agree to take part in PROPHER. 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. Your email address and mobile phone number will be deleted once your involvement in the study has ended.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

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

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- the University's Data Protection Officer at dataprotection@contacts.bham.ac.uk

What will happen with the results of the study?

Once **PROPHER** has finished we will publish the results in a medical journal so that other patients can benefit. We will also publicise the results on the study's website: www.escp.eu.com/research/cohort-studies/2019-patient-reported-outcomes-after-parastomal-hernia-treatment. No individual patients will be identifiable in any publications.

Who has reviewed the study?

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

Complaints

If you have any concerns, please speak to a member of the research team in the first instance, email propher@contacts.bham.ac.uk and we will do our best to answer your questions. If your concerns are not addressed and you wish to make a formal complaint then please contact Dr Birgit Whitman, email: researchgovernance@contacts.bham.ac.uk.

Chief Investigators:

Professor Thomas Pinkney, Professor of Surgical Trials, The University of Birmingham
Miss Sue Blackwell, Patient Representative and Co-Lead Investigator.
Email - propher@contacts.bham.ac.uk

Where can I get further information?

If you have any further questions about your treatment or this study, please discuss them with your surgeon, stoma care nurse, or local study investigator:

Name: .....

Tel No: .....

Position: .....

How to register for the PROPHER study

If you are happy to contribute to the study by answering our questionnaires, please scan the QR code or enter the following web address into your web search bar to gain access: https://bistc.redcap.bham.ac.uk/surveys/

And use the following unique study identification number:

- You will be asked to confirm you give consent to complete the questionnaires.
- You will also be asked to provide an email address to send the 3, 6 and 12 month questionnaires.

Thank you for taking the time to read this Patient Information Sheet