

Participant Information Sheet

GASTROS study

Standardising Outcome Reporting in Gastric Cancer Surgery Research

We would like to invite you to take part in a research study. Before you decide if you wish to participate, you need to understand why the research is being done and what it would involve for you. Ask us if there is anything that is not clear or if you would like more information.

What is the study for?

Gastric cancer (also known as stomach cancer) is the fifth commonest cancer in the world. The main treatment is surgery to remove all or part of the stomach, however we know that surgery can cause short and long term side-effects that impacts on patients in many ways. Research studies (trials) of new surgical treatments need to be able to measure how well a treatment works in treating the cancer, but also what side effects it may have and how they may affect patients. Researchers do this by measuring 'outcomes'. Examples of outcomes include 'overall quality of life' and 'complications' after surgery.

Identifying the best surgical treatments for gastric cancer patients involves comparing and combining results from different trials. At the moment, this is difficult to do because trials measure different outcomes and use different tests. Many of these studies often don't report how treatment affects a patient's quality of life.

We are developing a 'core outcome set' (COS) for surgical trials in gastric cancer. This is a list of outcomes that all surgical trials examining the treatment for gastric cancer should measure and report. Having a core outcome set will help to make sure that the results from all trials can be combined to get a better understanding of which surgical treatments are best. It will also help to ensure that outcomes such as 'side effects' and 'quality of life' are included in research studies. It is important that the outcomes included in a core outcome set are relevant to both doctors and patients.

We would like to interview patients to hear their views and experiences of living with and having treatment for gastric cancer. From this we hope to understand the outcomes which are most important to patients following surgery for gastric cancer.

Why have I been chosen?

You have been chosen because you have received or are currently receiving treatment for gastric cancer.

Do I have to take part in the study?

It is up to you whether you decide to take part or not. Not taking part will have no effect on the treatment you receive now, or in the future. If you decide to take part then later change your mind, you can withdraw at any time without giving your reasons.

What will I have to do if I take part?

If you agree to take part, you will be contacted by a member of the research team who will arrange a convenient time to meet and talk to you about your experiences of living with, and having treatment for, gastric cancer. This can take place either at your home, at Central Manchester University Hospital or at our MacMillan Centre in Manchester, whichever you prefer. A telephone interview is also possible should you prefer it. The conversation (Interview) normally takes between 30 minutes to one hour, but can be as long or short as you wish. Your conversation with the researcher will be recorded because it is difficult to take notes of what people say, listen carefully and think all at the same time. After the interview, the audio-recording is typed up so that we have a full and accurate account of the views that were presented.

Who will cover my expenses?

Any travel expenses you incur will be reimbursed by the research team.

What are the possible benefits of taking part?

There are no direct benefits to you taking part, but your views may help to benefit patients in the future.

What are the possible disadvantages of taking part?

You might find it upsetting to talk about your experiences of living with gastric cancer. However, if you do not wish to answer some questions that is alright. You can stop the conversation at any time you wish.

Will my data be confidential?

Yes. All information collected about you will be kept confidential. Information, including the audio recording and electronic versions of the transcript (written version of the conversation) will be labelled with a code instead of your name. Information collected will be kept securely, so that only the researchers and those who monitor the study can see it.

What if I want to make a complaint?

If you have a complaint about any aspect of the study, please contact a member of the research team via telephone or email:

Research Team Contact Details:

Nailah Brown, Study Coordinator

Email: nailah.brown@cmft.nhs.uk

Tel: 0161 275 6224

Who can I speak to about the study independent of the research team?

You can contact the Central Manchester University Hospital's Patient Advice and Liaison Service (PALS) on 0161 701 8711.

What will happen to the results of the study?

The results of the study will help to develop a core outcome set for use in gastric cancer surgery trials, aimed at deciding how effective a type of surgical treatment is. The results will be published in scientific and medical journals and presented at national and international conferences. You will not be identifiable from the published or presented results.

Who is funding and organising the study?

The study is funded by the National Institute for Health Research (NIHR) Doctoral Research Fellowship programme and is a collaboration between the University of Manchester and Central Manchester University Hospitals NHS Foundation Trust. The research is supported by the Medical Research Council's Hubs for Trials Methodology Research and is organised by the University of Manchester

Who has reviewed the study?

The East of Scotland Research Ethics Service REC 1, which has responsibility for scrutinising all proposals for research on humans, has examined the proposal and has raised no objections from the point of view of research ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from Central Manchester University Hospitals NHS Foundation Trust, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

What do I need to do next?

If you agree to take part, you need to provide your contact details to the research team by:

1. returning the reply slip supplied with this form, or
2. calling a member of the research team on 0161 275 6224, or
3. emailing nailah.brown@cmft.nhs.uk indicating that you are emailing about GASTROS.

A researcher will then telephone you to confirm you want to take part in the study. If you agree to be interviewed, we will arrange a convenient time and location. Before the interview, we will ask you to sign a consent form.

Further Information:

If you wish to find out more about the study, then please visit our website at www.GASTROSSStudy.org. The research team will be pleased to answer any questions and can be contacted via the details shown below:

Research Team Contact Details:

Nailah Brown, Study Coordinator

Email: nailah.brown@cmft.nhs.uk

Tel: 0161 275 6224

Bilal Alkhaffaf, Consultant Surgeon & Principal Investigator

Tel: 0161 901 2534

Email: bilal.alkhaffaf@cmft.nhs.uk

Reply Slip

(To be used if you prefer not to phone or email us on the details provided above).

If you would like to participate in this study, please sign and return this page to:

Nailah Brown

Central Manchester University Hospital Trust

University Research Floor (5th Floor)

St Mary's Hospital

Oxford Road

M13 9WL

I, would like to participate in the GASTROS study.

My contact telephone number or e-mail is:

Signed:

Date: ____/____/____