The ACCURE-UK Trial: The feasibility of undertaking Appendicectomy to impact upon the Clinical Course of Ulcerative Colitis

Patient Research Interview Information Sheet – ACCURE-UK non-participants
Version 2.0; 09-OCT-2014
Summary of an Invitation to take part in a research interview about the ACCURE-UK trial.

- You were approached to take part in the ACCURE-UK trial of a new treatment for your Ulcerative Colitis (UC), and preferred not to take part.

- This research interview study is trying to understand patients’ feelings about ACCURE-UK, particularly those who decided not to take part.

- Patients will meet with a researcher who is not a member of their clinical team and discuss the ACCURE-UK study.

- You do not have to take part in this research interview study, and if you decide not to, no-one will think badly of you and this will not affect the quality of your care in any way.

- Please take time to think about whether you want to take part in an interview. More details are provided below and a member of the research team will be happy to answer any questions.
An invitation to take part in a research interview about ACCURE-UK

You were approached to take part in the ACCURE-UK trial, but preferred not to take part. We are asking some patients who preferred not to take part in the ACCURE-UK trial if they would be willing to talk to a researcher about their experience and impressions of ACCURE-UK. **We are not asking you to reconsider taking part in ACCURE-UK, but are simply interested in your views about the trial.** The researcher you would talk to you will not be a member of the clinical team who are treating you. **If you decide to talk to a researcher, this short discussion would be confidential.** Before you decide whether to take part or not, you need to understand why this part of the research is being done, and what it would involve for you. Taking part in research is voluntary; it is up to you to decide to participate in this further study. You are free to withdraw at any time, and if you choose not to take part or to withdraw from the research, you 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.

Please take time to read the following information carefully. **One of our team will go through the information leaflet with you, explain the 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 them or another member of the local research team (see contact details .......). Talk to others about the study if you wish, such as friends or relatives, and take time to decide. If you would like to take part, you will be asked to confirm by signing a separate consent form and you will be given a copy to keep.
What is the purpose of the ACCURE-UK study?

ACCURE stands for: the feasibility of undertaking Appendicectomy to impact upon the Clinical Course of Ulcerative Colitis (UC). This is the UK arm of a group of studies that are being run here and in The Netherlands. The overall aim of the research is to find out whether removing the appendix (appendicectomy) can reduce the chances of a patient experiencing further flare-ups of their Ulcerative Colitis (UC) in the future months. This first phase of the research is called a feasibility study as it aims to explore whether this is an attractive treatment to offer to UC sufferers, both from the patients’ and the doctors’ point of view. If we can successfully recruit patients to this trial, and review them regularly throughout the one year period afterwards, we plan to undertake a follow-on trial in the future to establish exactly how beneficial this treatment is in a larger group of UC patients.

This part of the study is trying to understand the perspectives of patients who may not want to take part in studies like ACCURE-UK. This will be done by discussing these issues with patients (an interview). This is important so that the ACCURE-UK team can make sure that the research is designed and conducted in the best way possible. We are interested to hear what people understand about the study and what they were being asked to do.

Why am I being invited to take part in an interview?

You have been invited to take part because you were approached, but preferred not to take part in the ACCURE-UK trial.

Do I have to take part?

No. Taking part in any research is voluntary. If you decide to take part you will be given this information sheet to keep and later 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, then you don’t have to give any reason. Your care will not be affected in any way.

What will happen if I agree to take part in an interview?

We would like to talk to you in a single one-off interview.
Where will I meet the researcher?

You will meet the researcher at a time and place that is most convenient to you. For example, it may be most convenient if the researcher was to visit you at home or another venue of your choosing. Interviews will be conducted in quiet, confidential settings. If you decide to take part then the researcher will contact you to discuss and agree upon a time and place that is most convenient for you.

Will I be reimbursed for my travel expenses?

Yes. If you decide to meet at a location that isn’t at your home, you will be reimbursed for any travel costs incurred. To claim, please ask your researcher at the time of your meeting for further details.

How long will an interview last?

This is difficult to say exactly. Typically interviews can last 30-60mins, but can take longer depending on how much there is to discuss. It might be sensible to allow a little leeway just in case there is a lot to discuss.

What exactly will happen?

The researcher will meet with you, check that you understand all of the information about the study and that you are still willing to take part. They will then ask you to sign a consent form to confirm this. An interview is simply an informal discussion with the researcher.

The researcher will speak to you understand your perspectives on the the ACCURE-UK trial, for example, how the study was explained to you and what you know about what it is trying to achieve. **However, we are not trying to change your mind about taking part in ACCURE-UK.**

We are interested to hear your views and experience of the ACCURE-UK study so that we can make sure that any future research study looking at appendicectomy in ulcerative colitis is well designed. We would welcome your ideas about things that you feel the research team might need to consider during future studies from a patient’s perspective. It’s likely that the discussions will cover your illness and treatment more generally to understand how you feel the study fits in with that.
Will there be any long-term follow up?

No - you will be asked to take part in a single one-off interview.

Will information I give be confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Procedures for handling and storing your information will be compliant with the Data Protection Act 1998.

All information which is collected about you and that you give us during the course of the research will be kept strictly confidential. The information that will be collected includes personal information such as your name, address and NHS number, to allow us to keep in touch with you during your participation in the research. The information collected will be stored in a secure database held at the co-ordinating centre, and will only be accessed by authorised members of staff involved in the research. This includes the hospital research team and staff at the coordinating centre who are managing the research.

Your medical notes may need to be seen by authorised members of the hospital research team so they can collect information needed for this research study. Occasionally, other members of NHS staff or research staff may need to check your medical records. This will be done by NHS staff or by researchers who are bound by the same rules of confidentiality as all NHS staff. The confidentiality of your medical records will be respected at all times.

Under no circumstances will you be identified in any way in any report arising from the study.

What are the possible disadvantages and risks of taking part?

Taking part in this study will involve taking part in a single interview. We do not expect that the interviews will cause any distress or emotional discomfort but it is possible that you may discuss aspects of your illness that are upsetting to you. If you become upset the researcher will pause the interview to check that you are okay to continue, and if you wish they can move the discussion away from the topic that upset you. If you feel the interview is causing undue distress or emotional discomfort, you can end the interview at any time. The researcher will also have details of local counselling and clinical services on hand should you wish to receive further details of these.
What are the possible benefits of taking part?

Some people find that taking part in interviews helps them talk through their views and experiences, and that this can be helpful for them. The information we will get from the study will be very helpful to the NHS and to future patients with ulcerative colitis.

The discussions will be recorded – will they be confidential?

Yes. The interview conversations will be audio recorded, with your consent, so that the researchers can listen to them again and make a written record (transcript) of the discussion. Your name will not be used and we will remove information that we think might mean that other people can recognise you. Only the research team members will have access to the written accounts of the recordings.

The transcripts will be kept in a safe and secure place, so that they cannot be seen or heard accidentally or easily stolen. Similarly, audio files of the recordings will be held on secure encrypted equipment and computer networks at the University of Birmingham. You have the right to check the accuracy of data held about you and correct any errors.

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

You can decide not to continue with the interview study at any time but, if you do, we would still like your data to remain on file and be included in the final study analysis unless you specifically ask to be excluded.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If the harm is due to someone’s negligence, then you may have grounds for a legal action but you may have to pay for this. Whether or not you take part in the study, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you should ask to speak to the researchers involved in the study who will do their best to answer your questions (contact details are at the bottom of this form). 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). Taking part in the study would not affect your legal rights.
What will happen to the results of the study?

Researchers will review all of the results from the discussions to identify important themes and issues. We will report these to the wider research team so that they will influence any future research study of appendicectomy for ulcerative colitis. We will also report results to the funders of the research and hope to publish them in appropriate academic and professional journals and at conferences. We will provide you with a summary of the final results if you wish.

No individual patients will be identified in any publications. A copy of the published results of the study will be sent to all patients who have participated in an interview upon request. In line with clinical trial guidelines, at the end of the study, personal data will be securely stored for up to 5 years while research data will need to be securely archived for 20 years. Arrangements for confidential destruction will then be made. Should you withdraw consent for your data to be used, it will then be confidentially destroyed.

Who is organising and funding the research?

The ACCURE-UK study was developed by a group of doctors from across several hospitals and universities, including Birmingham, Leicester and Amsterdam. The study is coordinated by the ACCURE-UK study office at University of Birmingham Clinical Trials Unit and is sponsored by the University of Birmingham. The research has been approved and reviewed by all of these organisations.

Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people called the Research Ethics Committee to ensure your safety, rights, wellbeing and dignity. This study has been reviewed by the Tyne and Wear South Research Ethics Committee.

Where can I get further information?

If you have any further questions about this study or the interview please discuss them with a member of the research team (contact details given on the next page).
Details of research team member to contact:
Name...........................................................................................................

Job title...........................................................................................................

Contact Details..........................................................................................

The ACCURE-UK study office is located at the University of Birmingham Clinical Trials Unit, School of Health and Population Sciences, University of Birmingham, Edgbaston, Birmingham, B15 2TT. Web address: www.birmingham.ac.uk/ACCURE; e-mail: Accure@trials.bham.ac.uk