NIHR Global Health Research Unit on Global Surgery

Follow-up within global surgEry triAls: a qualiTative investigation to improvE trial Retention (FEATHER)

Participant information sheet (Adult)

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Background

Up to half of patients have a wound infection following abdominal ('tummy') surgery. Wound infections happen when germs grow in the wound causing it to become red, hot, and painful. The FALCON, ChEETAh and PENGUIN trials (for more information see trial Patient Information Sheet) is seeking to improve the way that we perform surgery around the world, and reduce the risk of wound infections for future patients. We are talking to you about this study, FEATHER, as you kindly gave consent to participate in the FALCON, ChEETAh or PENGUIN trial.

When studies are being designed to find out new knowledge to improve the health of patients ('research'), it is very important that the healthcare team collect all the required information about patients that enter into the study. If patients are not contactable after they leave hospital, it can lead to results that do not reflect the true benefits or risks of new treatments.

The purpose of FEATHER is to identify difficulties that patients may have in completing their follow-up over the telephone or returning to hospital for follow-up appointments, as well as finding potential ways to encourage patients to both participate and stay involved in research.

What this study entails

Whether or not you wish to take part in this study, no changes will be made to the treatment that you receive. A researcher will ask you about how easy you found it to return for research follow-up, why you chose to participate in the FALCON, ChEETAh or PENGUIN trial, and what encouraged you to stay involved after your operation. They will also describe several ways which could be used to encourage patients to stay involved in research, and they will ask for your views on whether or not this would work for your community. They will also talk to other patients who were part of the FALCON, ChEETAh or PENGUIN trial, like you, but were not able to return in-person for follow-up to learn from their experiences with an interview over the telephone. This study is being undertaken as a partnership with surgeons at *enter name of local hospital* and researchers at the University of Birmingham in the UK.

Time commitment

The time commitment for you is low. Whilst you are here at the hospital, at home or in the community or over a telephone or video call, we will ask some questions as part of interview. For most patients this lasts less than one hour, but it can be a little shorter or a little longer depending on how much there is to talk about. Once this interview is completed, your participation will be over, and nothing further will need to be done. Patients who participate in the study will receive a small token of thanks, such as reimbursement of their travel expenses to travel home.

Information to be collected

Only basic information will be collected. This will include information about your age, gender, whether you went to school or university, the type of job you do, the sort of area you live in, your experiences within the FALCON, ChEETAh or PENGUIN trial, and your thoughts about how we can encourage future patients to stay involved with research. We will keep this information separate from your name and address that was recorded for the FALCON, ChEETAh or PENGUIN trial. The researcher will ask for permission to audiotape their interview with you (this is optional). During the interview they may also make some notes. If any questions make you uncomfortable, you do not have to answer them. You can stop the interview at any time.

Confidentiality

Information about you will be kept safely. Personal data like your name, address and phone number are stored at your local hospital and not shared with anyone else. Only information that is essential for the research will

be sent to the University of Birmingham in England which is coordinating this study. This information will be stored for 10 years, and will then be deleted.

Consent

It is up to you whether you not you wish to join the study. If you agree to take part, we will ask you to sign (or fingerprint) a consent form. You are free to leave the study at any time, without giving a reason. We can remove your information from the study at any time up to seven days after your interview. Withdrawing from the study will not affect the care you receive from the doctors at your local hospital.