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# IntAct Perfusion Imaging Sub-study

**I**ntraoperative Fluorescence Angiography to Preve**nt** **A**nastomotic Leak in Re**ct**al Cancer Surgery

## PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT

A large-print version of this sheet is available on request.

**You have been invited to take part in the IntAct Perfusion Imaging sub-study.**

Before you decide if you want to take part in this optional imaging sub-study, we would like to explain why the research is being done, how we will use the information we have about you, and what the study will involve.

Please read this information carefully, and discuss it with others if you like. Ask us if anything is unclear, or if you would like more information.

**Once you have read this information, your doctor or nurse will talk to you about the study again and you can ask any questions you like.**

**How to contact us**

If you have any questions about this study, please talk to your doctor at

<<Enter PI, nurse name >>

<< Contact details for site>>

**Thank you for reading this information sheet.**

*This project is funded by the Efficacy and Mechanism Evaluation (EME) Programme, an MRC and NIHR partnership (project ref: 14/150/62)*

## What is the purpose of the sub-study?

The IntAct research team are undertaking this additional imaging sub-study to better understand why some patients suffer from anastomotic leak following rectal cancer surgery whilst others do not.

The perfusion imaging sub-study will use computed tomography (CT), a widely used imaging scan, to investigate differences in bowel blood supply between people, how previous radiotherapy (if performed) affects this blood supply and how this alters IFA assessment during surgery.

## Why have I been chosen?

You are being asked to take part in the IntAct perfusion sub-study because you have agreed to take part in the main IntAct trial and have been randomised to receive surgery with Intraoperative Fluorescence Angiography (IFA). The IntAct perfusion sub-study aims to recruit 75 patients in the UK.

## Do I have to take part?

No, your participation in the IntAct perfusion sub-study is voluntary. Your choice to participate or decline participation will not affect the treatment or care that you receive. In addition, it will not affect your participation in the main IntAct study, your relationship with the study investigators, or your future care.

If you decide to take part in this imaging sub-study you will be given this information document to keep. You will be asked to sign a consent form, but you are still free to withdraw at any time and without giving a reason.

## What will happen to me if I take part?

You will have two CT scans, additional to routine care, prior to your operation. This CT perfusion and CT angiography scan can be scheduled for the same visit and will take approximately 45 minutes of your time.

Copies of these scans will be sent from the hospital for central review by members of the IntAct research teams at Kings College London and Leeds Teaching Hospitals Trust via the Clinical Trials Research Unit.

## Unwanted effects of treatment

The CT scan requires the injection of an iodine containing contrast agent (dye) via a cannula placed in an arm vein. This dye is used widely in Radiology imaging but has some side effects. Mild effects include a warm flushing sensation. Significant but rarer effects are nausea, vomiting, a skin rash or an allergic reaction which may require further treatment.

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If you have experienced a previous allergic reaction to a radiological contrast agent (or other iodine containing medicine) or have poorly functioning kidneys it will mean you will be ineligible for the study.

**Ionising Radiation**

You will receive 2 CT scans prior to your operation which will be extra to normal care. These scans use ionising radiation to form images of your body and provides your doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous.

The radiation dose from the procedure can be compared to the small amounts of ionising radiation that we are all constantly exposed to in our daily lives due to natural background radiation in our environment. Rocks, building materials, food and drink, and cosmic radiation from space, all provide a radiation dose that we can't avoid. The radiation dose from the CT scans in this substudy will be the equivalent of about 16 years of natural background radiation. There is a 1:440 chance of developing cancer due to the additional ionising radiation in the future.

**Pregnancy:** It is important to tell your clinical care team if you are pregnant or planning to become pregnant as this may affect your care.

## What are the possible disadvantages and benefits of taking part?

The information from the trial will be helpful in guiding clinicians in choosing the best treatment for patients with rectal cancer and by better understanding the blood supply to the bowel it is hoped that it can make surgery safer in the future by minimising the occurrence of anastomotic leaks. However there will be no immediate benefit to you in taking part in this imaging study because the results will not be known before the end of the trial. Participation in the study will not affect the normal management of your condition.

## Will my taking part be kept confidential?

If you decide to participate in the IntAct sub-study, the information collected about you will be handled strictly in accordance with the consent you have given and also the 1998 Data Protection Act.

Your full name will be included on your consent form and a copy of this will be sent to the Clinical Trials Research Unit (CTRU) at the University of Leeds.

Copies of the two scans taken prior to your operation will be sent from the hospital for central review by members of the IntAct research teams at Kings College London and Leeds Teaching Hospitals Trust through standard post, courier or electronic transfer via the Clinical Trials Research Unit. The CT

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scans will only be labelled with your IntAct trial number, date of birth and initials. Data from the central review will be collected on paper forms and send to CTRU. Again only your IntAct trial number, date of birth and initials will be recorded on these forms to ensure the correct information corresponds to the correct patient. Data will be entered onto a secure database held at the CTRU in accordance with the 1998 Data Protection Act.

Every effort will be made to ensure that any further information about you that leaves the hospital will not identify you directly e.g. your name and address removed so that you cannot be recognised from it; this information will usually be removed by a member of the trial team at your hospital, or at the CTRU upon receipt.

The information collected about you may be shared with other research teams to answer new research questions in the future. however this information will be fully anonymised.

## What will happen to the results of the research trial?

When the trial is complete the results will be published in a medical journal, but no individual participants will be identified. The results may also be summarised on the internet- these results will not identify any individual participants. If you would like to obtain a copy of the published results, please ask your surgeon.

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| | |
|---|---|
| Participant ID: | Initials: |
| Date of Birth: | NHS/Hospital Number: |
| ISRCTN: | Principal Investigator: |

# IntAct Perfusion Sub-Study:
# Intraoperative Fluorescence Angiography to Prevent Anastomotic Leak in Rectal Cancer Surgery

## PARTICIPANT CONSENT FORM

***Please initial each box***

1. I confirm that I have read and understand the information sheet for the above trial and have had the opportunity to ask questions ☐

2. I agree to allow any information or results arising from this sub-study to be used for healthcare and/or further medical research upon the understanding that my identity will remain anonymous wherever possible. ☐

3. I agree to a copy of this Consent Form being sent to the CTRU. ☐

4. I agree to take part in the IntAct Perfusion sub-study. ☐

**Patient:**

Signature……

Name (block capitals)……

Date……

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**Investigator:**

I have explained the trial to the above named patient and he/she has indicated his/her willingness to participate.

Signature……

Name (block capitals)……

Date……

**(If used)Translator:**

Signature……

Name (block capitals)……

Date……

(1 copy for patient; 1 for the CTRU; 1 held in patient notes, original stored in Investigator Site File)

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