

REMOTE PRELIMINARY EMAIL

Dear [insert PI name],

Thank you for your interest in the SWIFFT trial, which we are now ready to start setting up at your local hospital site. Provided you would still like to act as the local Principal Investigator in [insert site name], this email provides details of the next steps that we need take to prepare an application for the approval of the study to your local Research and Development (R&D) department.

Following approval, we will meet with you and the team to talk through the trial processes in detail and provide training so that you are ready to start patient recruitment. First, could you please follow these steps so that we can submit the application to R&D:

1. Please familiarise yourself with the trial flowchart (attached), which highlights the process of recruiting and following up patients into the trial. The trial protocol is also attached for further information. Please note that patients eligible for the trial are those aged 16 or above, presenting within two weeks of their injury with a radiologically confirmed bicortical fracture of the scaphoid waist.
2. Key elements of importance to the running of the trial at each site are outlined in the Memorandum of Understanding for sites (attached). Please confirm that these elements of the trial will be feasible locally, in particular the following:
 - a. Obtaining baseline CT scans before randomisation whenever possible, and at the very latest, within 2 weeks of injury and, in the surgery group, before surgery.
(Please note that there is funding available to reimburse the hospital for expenses arising from X-rays and CT that are undertaken for research purposes, and for the time required to complete study forms)
 - b. That all patients randomised to the surgery group will receive an operation within 2 weeks of presentation to A&E.
3. We will need to consider how you foresee that patients in [insert site name] will be identified and approached about the study (e.g. frequency and timing of fracture clinics, availability of research nurse to discuss the trial with patients and complete study procedures). Below we indicate the pathway we advise for recruiting patients into the trial. Please let us know if this is feasible and provide details of your proposed pathway, or a date and time when I can contact you to discuss in more detail via telephone.
 - Patient presents to A&E and has the required series of X-rays (*this is currently 5 views, however this is subject to an amendment and by the time your site is set up, patients should be able to be screened on the basis of the usual series of x-rays in A&E, with any additional x-rays required for outcome assessment taken after patient consent*);
 - Patient's wrist is immobilised using plaster or splint and referred to the next fracture clinic;
 - The following day after presentation in A&E the designated person should attend the post-trauma X-ray review meeting (if held) to ascertain patient's eligibility;
 - If it appears that the patient is eligible then the designated person should establish when the patient is attending the fracture clinic and should notify the X-ray Department that a slot may be required for the patient to have their CT scan on that day;
 - The designated person should then attend the fracture clinic in order to re-confirm with the orthopaedic surgeon whether the patient meets the inclusion criteria before approaching the patient to take part.

4. If you have a research nurse or research physiotherapist in mind to help with this study, please forward their contact details.
5. We will need to liaise with the x-ray department about the additional X-rays and CT scans required for the study, please forward the contact name of the appropriate person in the x-ray department.
6. We will need CVs for yourself and anyone that may be involved in consenting patients into the trial (e.g. other surgeons and a research nurse/physio). Please complete the CV template attached.
7. We will also need GCP certification for people who will be involved in consenting patients. The Sponsor's requirement is that the GCP certificate is less than two years old. Please forward scanned copies of these, and if you do not currently have training in Good Clinical Practice (GCP), please let me know and I can help to arrange this.
8. If you (or a research nurse) currently have an IRAS account then please provide IRAS account details to us so that we can forward the Site Specific Information form to be submitted to your local R&D department for electronic signature when it has been prepared.

As we aim to start recruitment into [insert site] in [insert estimated start date], we will need this information as soon as possible so that we can submit the R&D application by, at the very latest, [insert timescale].

Thank you in advance for your support and time,

With best wishes,

[Insert name]

FACE-TO-FACE PRELIMINARY EMAIL

Dear [insert PI name],

Thank you for your interest in the SWIFFT trial, which we are now ready to start setting up at your local hospital site. Provided you are still interested in being the local Principal Investigator in [insert site name], this email provides details of the next steps that we need take to prepare an application to your local Research and Development (R&D) department.

We would like to arrange a meeting with you and colleagues involved in the study to discuss these steps (detailed below) in more detail prior to submitting the study for local R&D approval. Ideally, we would like the following people to attend this meeting:

- You, as the Principal Investigator
- The research nurse / research physio that will be involved in the trial (if you have one locally)
- Any surgical colleagues that will be involved in the study
- Radiology contact person
- R&D contact person

When would be a convenient time to meet? Ideally, in order for us to progress with the application and start recruitment in [insert site name] as soon as possible, this meeting would need to take place by [insert timescale].

Thank you in advance for your support and time, I look forward to working with you.

With best wishes,

[Insert name]

Steps prior to R&D application:

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 - a. Obtaining baseline CT scans whenever possible before randomisation, and at the very latest, within 2 weeks of injury and, in the surgery group, before surgery.
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 - Patient's wrist is immobilised using plaster or splint and referred to the next fracture clinic;
 - The following day after presentation in A&E the designated person should attend the post-trauma X-ray review meeting (if held) to confirm that the patient meets the inclusion criteria;
 - If it appears that the patient is eligible then the designated person should establish when the patient is attending the fracture clinic and should notify the X-ray Department that a slot may be required for the patient to have their CT scan on that day;
 - The designated person should then attend the fracture clinic in order to re-confirm with the orthopaedic surgeon whether the patient meets the inclusion criteria before approaching the patient to take part.
4. If you have a research nurse or research physiotherapist in mind to help with this study, please forward their contact details.
 5. We will need to liaise with the x-ray department about this study and the additional X-rays and CT scans that are required, please forward the contact name of the appropriate person in the x-ray department.
 6. We will need CVs for yourself and anyone that may be involved in consenting patients into the trial (e.g. surgeons and a research nurse/physio). Please use the CV template [attached](#) to complete.
 7. We will also need GCP certification for the people involved in consenting patients. The Sponsor's requirement is that the GCP certificate is less than two years old. Please forward scanned copies of these, and if you do not currently have training in Good Clinical Practice (GCP), please let me know and I can help to arrange this.
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