

**Site visits – checklist**

Site:

| Pre-approval visit / email correspondence         |   |  |
|---|---|--|
| <b>1. Describe study</b>                          | Outline inclusion and exclusion criteria  |  |
|   | Discuss flowchart of patient recruitment and outline responsibilities of the site for follow up   |  |
| <b>2. Discuss current procedures</b>              | Map out current flow of patients at this hospital, from start to finish (produce flowchart)   |  |
|   | How many surgeons do scaphoid surgery?  |  |
|   | Do they have a research nurse already?  |  |
|   | The type of hospital (e.g. general, teaching)?  |  |
|   | When do the fracture clinics take place (ward patients should also be considered)?  |  |
|   | The expected throughput of eligible patients in a typical month   |  |
|   | The pre-trial rate of surgery for these potentially eligible patients (if this is not roughly 50/50 we need to consider: 1) is the site in equipoise? 2) do we need to negotiate with the Trust about funding additional treatment costs?)  |  |
|   | Current rehabilitation provision  |  |
|   | Does the hospital have access to a goniometer and Dynometer for the grip & range assessment? If so, we ask that sites label one machine as a SWIFFT machine, so that it can be calibrated and the same machine used for each patient and each measurement. If not, we can look into providing these machines to sites.                                    |  |
| <b>3. Radiology involvement</b>                   | Current use of radiograph views (clarify which)   |  |
|   | 5 radiographic views required – see handout – at baseline, 6, 12, 52 and 5 years  |  |
|   | CT required at baseline, 52 and 5 years   |  |
|   | At baseline the CT scan <b>MUST</b> be undertaken within 2 weeks of injury. In the surgery group it is essential that this is also undertaken before surgery. The CT should be scheduled (and where possible undertaken) before randomisation takes place. For example, this could be arranged using pre-booked slots that coincide with fracture clinic. |  |
|   | The CT scan should <b>not</b> be uploaded onto the hospital PACS system as this is only being undertaken for research purposes and should not be viewed by the treating clinician.  |  |
|   | Decide procedures for forward x-rays and CT images to York (whether RN or radiography will do this)   |  |
|   | Details of someone in Radiography who we can liaise with  |  |
| <b>4. Obtain agreement for trial requirements</b> | The PI to sign off on the memorandum of understanding. This includes various requirements for hospital sites participating in the trial, including (but not limited to) the following:  |  |
|   | The eligibility must be confirmed by the orthopaedic surgeon (the form can be completed by the RN)  |  |
|   | The surgeons agree to use established techniques with which they are already familiar   |  |
|   | The competence of the operating surgeon in the surgical procedure that is performed   |  |
|   | All surgeons must accept that they should not introduce radically new methods (or methods they are unfamiliar with) during the trial  |  |
|   | Hospital sites must agree to undertake no other trials of scaphoid fractures during the study period  |  |
|   | Agree that patients randomised to surgical treatment will be operated on within 2 weeks of presentation   |  |
|   | Liaise with A&E (with support of the PI) to ensure that no treatment advice is given to patients before they arrive in fracture clinic  |  |
|   | Agree to undertaking follow-up clinic reviews (grip and range and radiography) at 5 years   |  |
|   | Radiographers agree to undertake required radiographic views and CT   |  |

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| <b>5. Discuss finances for the trial</b>       | £610.99 in total for eligible and randomised patients followed up for 5 years (£446.67 plus £164.32 for five year follow up)/      |  |
|  | £7.32 for screening costs (completion of eligibility form and consent status form)   |  |
|  | £148.96 for randomised patients at baseline (patient questionnaire, grip and range form and cost of CT scan)                       |  |
|  | £41.85 hospital data at 6 weeks (grip and range form, surgery form, complications form)  |  |
|  | £41.85 hospital data at 12 weeks (grip and range form, complications form)   |  |
|  | £178.96 hospital data at 52 weeks (grip and range form, complications form, cost of X-rays and CT scan)                            |  |
|  | £164.32 hospital data at 5 years (grip and range form, cost of X-rays and CT scan)   |  |
| <b>6. Obtain items for R&amp;D application</b> | Need CVs of all relevant people  |  |
|  | All important members of the team will need to be mentioned in the SSI application – check who these are and their contact details |  |
|  | IRAS email for sending the SSI form to sign electronically   |  |
|  | GCP training for PI and designated person – need certificate (issued within past 2 years)  |  |
|  | Agree Clinical Trial Agreement and obtain signature from PI, Sponsor and Trust R&D   |  |
|  | Trust logo   |  |
|  | PALS contact for the Participant Information Leaflet   |  |

**Site set up visit**

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| <b>A. Introduce the site file</b>            | Provide Investigator Site File (this should be a complete copy of the Master Trial Site file but specific to the participating site)                                |  |
|  | Provide three copies of the Trial Site Manual (one copy for Principal Investigator; one copy for designated person; one general copy)                               |  |
|  | Provide laminated copies of the flowchart (one copy for the Principal Investigator; one copy for designated person; one copy each for other participating surgeons) |  |
|  | Explain about amendments and ethics approval info that needs to be kept up to date  |  |
|  | Contains extra A&E leaflets etc   |  |
|  | Need to complete the participant status log (including for ineligible and non-consenting patients)  |  |
|  | Need to complete the staff delegation log (send to YTU when done and if any new members added)  |  |
|  | Check we have CVs of all relevant people (i.e. if any new team members)   |  |
|  | Provide 20 copies of the pre-randomisation packs  |  |
|  | Explain post-randomisation packs – who (address) should these be sent to?   |  |
| <b>B. Discuss trial processes</b>            | Outline inclusion and exclusion criteria  |  |
|  | Discuss flowchart of patient recruitment and outline responsibilities of the site for follow up (see forms below at baseline, 6, 12, 52 weeks and 5 years)          |  |
|  | <b>Reiterate trial requirements outlined in Sections 1,3 and 4 above</b>  |  |
| <b>C. Discuss each form in the site file</b> | Trial poster  |  |
|  | Guidance document for X-ray views   |  |
|  | Study Eligibility form  |  |
|  | Guidance document on taking informed consent  |  |
|  | Patient Information Leaflet for the trial   |  |
|  | Consent Status Form   |  |
|  | Trial Consent Form  |  |
|  | Patient contact details form (x2)   |  |
|  | Qualitative study Information Leaflet   |  |
|  | Qualitative Consent Form for non-consenting participants  |  |
|  | SWIFFT Baseline Form  |  |
|  | Grip and Range Form (to be completed at baseline, 6, 12, 52 weeks and 5 years)  |  |
|  | Guidance document on measuring wrist ROM and grip strength  |  |
|  | Home Exercise Information Sheet   |  |
|  | Complications Form (to be completed at 6, 12, 52 weeks and 5 years)   |  |
|  | Surgical Form (to be completed during surgery and returned by 6 weeks)  |  |
|  | Treatment Confirmation Form (at 6 weeks)  |  |
|  | Adverse Event Reporting Form – explain SAEs: 24 hrs and NSAEs: 5 days (send by fax and telephone in advance)  |  |
| Patient change in status form                |   |  |
| Example patient postal questionnaire         |   |  |
| <b>D. Discuss finances for the trial</b>     | <b>See section 5 above for breakdown per patient at each stage of the trial</b>   |  |
|  | Need contact details for the PO so that York/Leicester can forward payments   |  |