

SWIFFT

Scaphoid Waist Internal Fixation for Fractures Trial

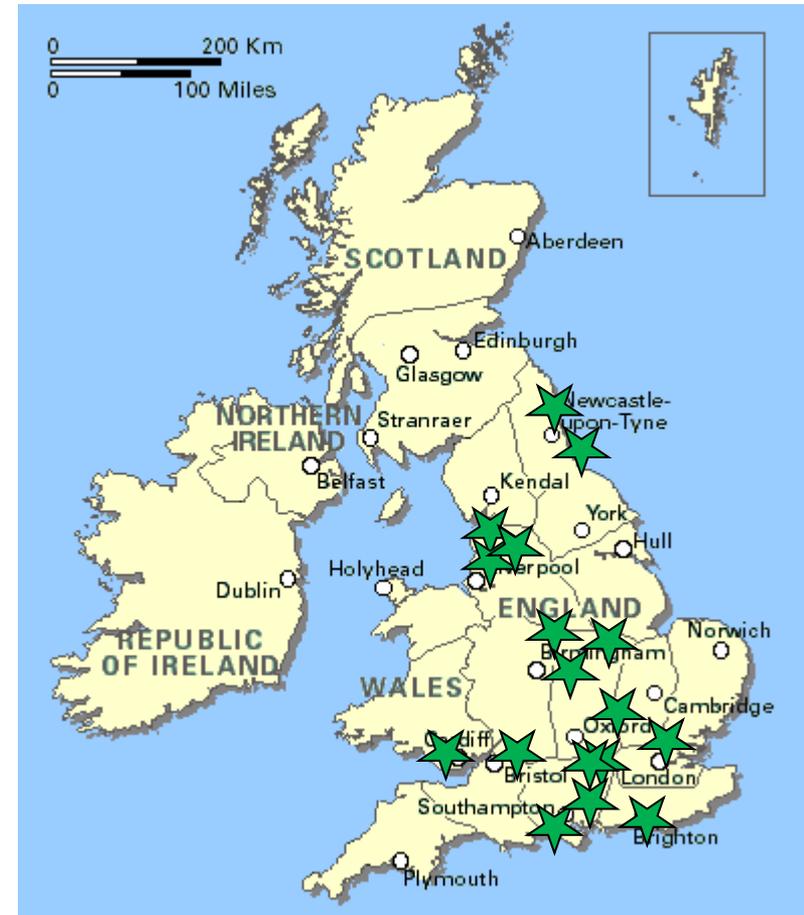
PRELIMINARY SITE VISIT
Bristol Royal Infirmary
25th April 2014

Trial Organisation

- **Chief Investigator:** Professor Joe Dias (Leicester)
- **Trial Manager:** Dr Stephen Brealey (University of York Trials Unit)
- **Trial Coordinators:** Dr Laura Jefferson, Mrs Liz Cook and Dr Garry Tew (University of York Trials Unit)
- **Collaborators:** University of Leicester, University of Nottingham & Trusts (South Tees, Bolton, Coventry)
- **Sponsor:** University Hospitals of Leicester NHS Trust
- **Funding Body:** NIHR Health Technology Assessment Programme

Trial Design

- Pragmatic, multi-centre, RCT
- Comparison of surgical fixation vs initial cast immobilisation of acute scaphoid waist fractures followed by fixation of only the 10-12% that fail to unite
- Patients aged 16 and above presenting within 2 weeks of injury
- Recruitment: 438 participants
 - 17 sites currently set up
 - In process of setting up additional 15 sites



Regulatory & Ethical Approvals

REC Favourable Opinion granted on 21 May 2013

- Minor Amendment 1 - REC Favourable Opinion dated 13Jun2013 (update to protocol, PIL and consent form)
- Minor Amendment 2 - REC Favourable Opinion dated 10Jul2013 (update to trial poster)
- Minor Amendment 3 - REC Favourable Opinion dated 29Aug2013 (update to PIL and consent form)
- Minor Amendment 4 – REC Favourable Opinion dated 17Sept2013 (update to sites)
- Minor Amendment 5 – REC Favourable Opinion dated 11Oct2013 (update to sites)
- Substantial Amendment 1 – REC Favourable Opinion dated 03Dec2013 (changes to eligibility, consultant obtaining consent, X-ray requirements and Baseline PRWE)
- Minor Amendment 6 – REC Favourable Opinion dated 14Jan14 (additional site, change to eligibility criteria, adverse event reporting and identification from satellite sites)
- Minor Amendment 7 – Due to be submitted this week (addition of beighton laxity measurement to protocol and change in G&R to slot 2)

NHS R&D approval – application being prepared. 30 days to process once submitted.

Eligibility assessment

First consider



Inclusion criteria

- Adults aged 16 or above and skeletally mature
- Presenting to the participating trauma centre within 2 weeks of their injury
- Diagnosis of a bicortical fracture of the scaphoid waist

Exclusion criteria

- a) Displacement of fracture >2 mm
- b) Concurrent wrist fracture in the opposite limb
- c) Trans-scaphoid fracture dislocation
- d) Multiple injuries in the same limb
- e) Patient not resident in the trauma centre catchment area of a participating site
- f) Patients who lack mental capacity
- g) Patient is pregnant

For eligible patients...

- Discuss the trial with the patient and attempt to consent (see advice booklet)
- If the patient consents, complete the baseline forms and then randomise the patient.
- If the patient does not consent, open the qualitative study pack and discuss this with the patient. If they consent to these interviews, complete the consent form and contact details form.
- The Nottingham researcher will be responsible for undertaking interviews.

There are therefore 4 types of eligible patients:

1. Consenting TRIAL patients who AGREE to the qualitative interviews
2. Consenting TRIAL patients who DECLINE the qualitative interviews
3. NON-TRIAL patients who AGREE to the qualitative interviews
4. NON-TRIAL patients who DECLINE the interviews

Identification of patients locally

- Regularity of fracture clinics, consider the following:
 - RN availability
 - Frequency to meet key timeframes for study (identification and CT within 2 weeks from injury, and surgery within 2 weeks from A&E presentation)
- Availability of CT at baseline (see next slides on feasibility)
- Current x-ray views

SWIFFT

Version 5.0 (07/01/14)

SWIFFT Trial: Memorandum of Understanding

Thank you for agreeing to take part in this research. We will have discussed and already agreed the areas mentioned below. The Principal Investigator should now initial and sign this form to confirm agreement and understanding of the key requirements of the SWIFFT trial (relating to protocol Version 2.1 (06/01/14)).

Local trial publicity and training

- I agree that no other trials or studies of the scaphoid waist will be undertaken during the recruitment period for the trial (exceptions may be made of previously established on-going studies or trials provided these have been agreed).
- I will ensure appropriate training of designated contacts for co-ordination and implementation of the trial, including the completion of the trial forms and distribution of these and other trial materials.
- I will ensure all clinical staff involved in the care of the patients with fractures of the scaphoid waist are well informed about the trial. This includes the local A&E department, to ensure no treatment advice is given before arrival in clinic.
- I will ensure that no identifiable patient data is used in communications about trial participants

Identification and consenting of patients

- I will ensure that there is a clear agreed process, aligned to local circumstances, to identify potential participants.
- I will ensure that assessment of eligibility is done within an agreed period to avoid delay and that this will be undertaken by an orthopaedic surgeon.
- I will ensure that timely and ethically approved methods are used to acquire informed consent from all eligible patients.
- I will ensure that potential participants are informed about the qualitative sub-study when the trial is introduced.

Radiology

- I will ensure that in agreement with the local radiology department the following X-rays views are performed for all consenting patients at baseline: the semi-supine oblique, the semi-prone oblique, the elongated scaphoid (Ziter or Ziter type) view
- I will ensure that in agreement with the local radiology department the following views are performed at 52 weeks and 5 years: posterior-anterior, lateral, semi 45° supine, semi 45° prone and the elongated scaphoid (Ziter or Ziter type) view.
- I will ensure CT scans as described in the manual are completed for patients recruited into the trial, at baseline, 52 weeks and 5 years.
- I will ensure in agreement with the local radiology department that the baseline CT scan is obtained before randomisation. If this is not feasible, at the very latest this should be undertaken **within 2 weeks of injury** and, in the surgery group, **before surgery**.
- I will ensure that the baseline CT scan is **not** accessible by the treating clinician (either by password protection or not uploading onto the hospital PACS system) as this is only being undertaken for research purposes.
- I will ensure all fractures are confirmed with the treating clinician following review of CT scans and prior to treatment commencing.
- I will ensure that **anonimised** copies of X-rays and CT scan will be forwarded to York Trials Unit in a timely fashion.

Surgery

- I agree that all patients randomised to the surgery group will receive an operation **within 2 weeks of presentation to A&E / other satellite referral centres**.
- For the duration of the trial, I agree that surgical treatment methods for the treatment of scaphoid fractures will follow usual routine care.
- I will ensure that the surgeons participating in the trial are experienced in the treatment of fractures of the scaphoid waist and accept that they should use techniques with which they are familiar.
- I will ensure any trial participants in the 'initial cast treatment' group, whose fractures have failed to unite, will receive surgical fixation within appropriate usual care timescales.

Hospital followup

- I will ensure that clinic reviews are completed with participating patients at 6, 12 and 52 weeks and 5 years to assess wrist range of movement and grip strength (and obtain X-rays/CT scans).
- I will ensure the York Trials Unit are notified within appropriate timescales adverse events and of any deviations in trial procedures.

Name of Principal Investigator:

Name of Hospital:

Signature of Principal Investigator:Date:

Radiology: requirements

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- I will ensure all fractures are confirmed with the treating clinician following review of CT scans and prior to treatment commencing.
- I will ensure that masked copies of X-rays and CT scan will be forwarded to York Trials Unit in a timely fashion.

Surgery: requirements

- I agree that all patients randomised to the surgery group will receive an operation within 2 weeks of presentation to A&E / other satellite units (e.g. walk in centres or cottage hospitals).
- For the duration of the trial, I agree that surgical treatment methods for the treatment of scaphoid fractures will follow usual routine care.
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Next steps

- Prepare application to local R&D department.
Required documents:
 - CVs
 - GCP certificates
 - Trust logo and PALs/R&D contact for PIL
 - Agree content of SSI form and PI to sign electronically
 - Signed CTA
- Site Initiation Visit (agree date and see next slide)
- Await R&D approval
- Start recruitment!

Site Initiation Visit

The following will be supplied:

- Trial Site Manual
 - Investigator Site File (containing delegation Log)
 - Pre-randomisation packs - comprises the following forms:
 - ***Study Eligibility Form***
 - ***Patient Information Leaflet for the trial***
 - ***Consent Status Form***
 - ***Consent Form for Trial***
 - ***Trial Contact Details Form***
 - ***Baseline Form***
 - ***Wrist Range of Movement and Grip Strength Form***
 - ***Surgery Form***
 - ***CD for return of X-rays and CT scan***
- Separate envelope for:*
- *Non-trial Interview Contact Details Form*
 - *Linked Interview Information Leaflet*
 - *Consent form for linked interview patients*

Any Questions?

.....at all?