

Lateral Compression Type-1 Fracture Fixation in the Elderly



Trial Newsletter: Issue No. 3, May 2020



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COVID-19: IMPACT ON TRIAL ACTIVITIES

Due to the COVID-19 pandemic, the sponsor, funder, and trial team made the decision to suspend screening and recruitment of patients into L1FE, effective 19th March 2020. This suspension of trial activities will remain in place for 6 months, with a review at 3 months. We aim to restart recruitment to the L1FE study by 1st November 2020, or earlier if possible.

All patients currently in the L1FE trial will be followed up remotely (by telephone). This includes the 12-week follow-up, unless a patient is already attending hospital for another reason. Sites with patients currently in the trial, have received advice on patient follow-up and Adverse Event reporting, but if you have any further questions please do not hesitate to contact the trial team.

For more information on contacting the trial team while we are working from home, please see the section 'Keeping in Touch'. We appreciate that as clinical staff you have faced, and will continue to face, challenging and unprecedented circumstances at work. We sincerely appreciate your ongoing support with the L1FE study, and the vital role you play as key workers in the NHS. We wish you all a safe and healthy next few weeks.



RESEARCH STAFF TELECONFERENCE

The first L1FE Research Staff Teleconference on the 1st April 2020 was a great success and was attended by 9 researchers from 9 different sites. Thank you to everyone able to join us despite the current circumstances. For your reference, we have also attached the teleconference minutes.

A central theme that emerged from the discussion was a greater need for clarity regarding inclusion/exclusion criteria; particularly, the required timing of events, patient (in)ability to mobilise, and low energy vs. high energy fractures.

During this unexpected 'break' from screening and recruitment activities, the trial team are undertaking a critical review of trial processes, paying particular attention to the concerns and questions raised at the meeting. Your contributions to this discussion have been extremely valuable and are helping us to better understand how we can provide additional support and greater clarity to participating sites, in order to improve recruitment rates when the trial is able to restart. If you were not able to make it and would like to discuss your experience of screening or recruitment for L1FE, don't worry; you can contact the L1FE team at anytime (see Staying in Touch). We will ensure that any changes to procedures or clarifying materials developed as a result of the teleconference will be trial wide, and we hope all sites will benefit from these. Sites present at the teleconference wanted to have a better idea of screening data up until now, so we have provided these numbers in the next section.



SCREENING DATA

Overall screening and recruitment metrics (updated 14/05/2020 with data up to 20/03/2020)*

| Site | Patients screened | Number of eligible patients | % Eligible | Number of patients approached | % Approached out of eligible patients | Number of patients consented | % Consent of approached eligible patients |
|----------------|-------------------|-----------------------------|------------|-------------------------------|---------------------------------------|------------------------------|---|
| Royal London | 36 | 13 | 36% | 12 | 92% | 7 | 58% |
| Addenbrookes | 11 | 1 | 9% | 1 | 100% | 0 | 0% |
| Bristol | 61 | 5 | 8% | 2 | 40% | 1 | 50% |
| Nottingham | 12 | 0 | 0% | | | | |
| South Tees | 10 | 2 | 20% | 1 | 50% | 1 | 100% |
| Oxford | 2 | 0 | 0% | | | | |
| Cardiff | 6 | 1 | 17% | 1 | 100% | 0 | 0% |
| Coventry | 4 | 0 | 0% | | | | |
| King's College | 5 | 1 | 20% | 0 | 0% | | |
| St Georges | 9 | 6 | 67% | 5 | 83% | 0 | 0% |
| St Marys | 21 | 1 | 5% | 1 | 100% | 0 | 0% |
| Total | 177 | 30 | 17 | 23 | 77 | 9 | 39 |

*Please note there are a number of reasons for variability in numbers between sites, including a wide range of site set-up/opening dates



SCREENING DATA

Reasons for exclusion (more than one reason per patient possible; including eligibility forms received and processed by 19/03/2020)

| Exclusion Criteria | Number excluded, n (%) |
|---|-------------------------|
| | Processed data, n = 108 |
| a. Unable to schedule surgery to be performed within 10 days of injury | 12 (11.1) |
| b. Surgery is contra-indicated because patient is not fit for anaesthetic (spinal or general) or soft tissue concerns | 16 (14.8) |
| c. Patients who were non-ambulatory or required assistance walking, with or without a walking aid prior to their injury | 7 (6.5) |
| d. Concomitant injury or poly-trauma that impedes mobilisation | 21 (19.4) |
| e. Fracture configurations not amenable to internal fixation with or without ilio-sacral screws | 4 (3.7) |
| f. Patient is less than 60 years old | 3 (2.8) |
| g. Patient does not have a low energy LC1 pelvic fracture, arising from a fall from standing height or less | 8 (7.4) |
| h. Patient is able to mobilise independently or with supervision (with or without a walking aid) to a distance of around 3 metres and back due to pelvic pain or perceived pelvic pain after 72 hours post injury | 66 (61.1) |
| i. Other (of which no other reason (a to h) was given) <ul style="list-style-type: none"> – Patient non-compliant with ward interventions – consent approach likely to aggravate – Patient had dementia and was already non-compliant with nursing care and rehabilitation – Patient considered to be unsuitable for surgery | 3 (2.8) |

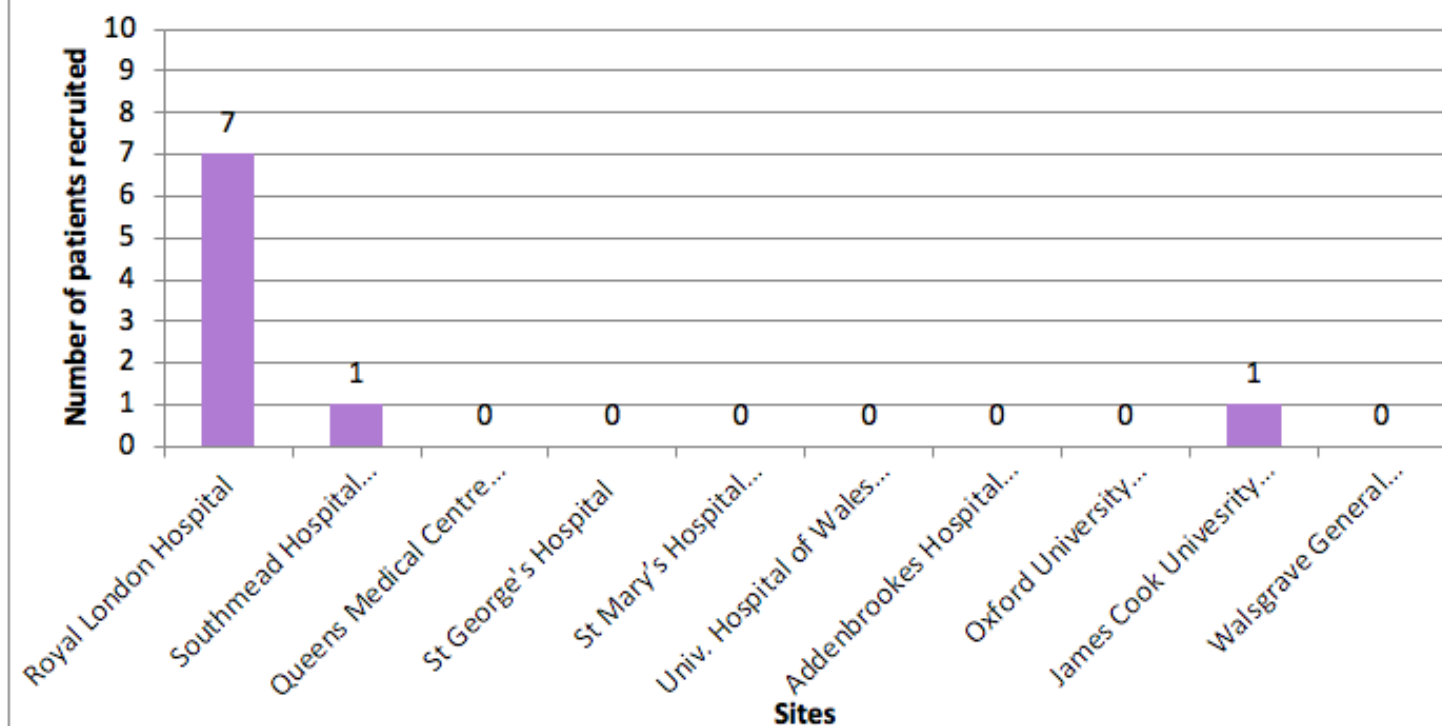


SITE SET-UP / RECRUITMENT UPDATE

Congratulations to **The Royal London Hospital** for being our top recruiter of the month! 1 further participant has been recruited in February and we have a total of 9 study participants.

There are 11 open sites and we look forward to opening further sites when we are able to resume trial activities.

Total Number of Patients Recruited by Site (in order of date set up)



COMING SOON...

Substantial Amendment 1 was submitted in February and received HRA approval on 10th May. This amendment included changes to various documents, which we will be sending out to all sites soon. Please look out for these.

In an effort to address some of the issues raised at the teleconference, and to further clarify trial procedures, we have been busy writing and creating/filming videos for you! We are really looking forward to sharing the finished products with you, so please keep an eye out for this!

KEEPING IN TOUCH

Please do keep us updated with any developments or arising restrictions at your site. The L1FE trial team are working from home and are unavailable on our usual office numbers. Therefore, until further notice, the best way to contact us for any concerns or queries is at our usual emails. If you would like to discuss anything by phone, please let us know the best number to call you on and we can make outbound calls as required.

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