



A message from the CI:

The last few months have been a tricky time for us all. We hope that you, your teams and your families are keeping safe and well.

As you will know, we took the decision to put recruitment to the study on hold in mid-March. We are writing to bring you an update on all aspects of the study, and also to confirm that we aim to restart recruitment to the study on 13th July 2020. We understand that sites across the country have had a very different experience of COVID and will be in very different positions with regards re-engaging with the study. The coordination team will be there to support you through this process. This is simply the first stage in allowing sites to recruit & randomise patients where this is possible. It's hard to know how the landscape for gallbladder surgery and research will be changed by the pandemic, but we will be sure to keep you informed. Many thanks as always for your support of the study.

Prof Giles Toogood, Chief Investigator



CRF Changes

You will soon receive a separate communication from us regarding upcoming changes to the study CRFs. The main change with the new version 4.0 of the main CRF pack is the introduction of 3 new pre-operative forms. These forms are designed to capture information on pre-operative admissions. We will ask that you complete these forms retrospectively for all patients who have been admitted for lap chole, and then continue this data collection going forward. We apologise for the additional work caused by this. There have also been some small changes to other forms, mainly around the way in which patient deaths are collected. Do get in touch if you have queries about any of these changes.

Recruitment Restart

The study will restart recruitment where possible on **13th July 2020**. We will be in contact with you to see what study activity, if any, your site could restart from this date.

COVID-19

It's hard to tell what impact COVID-19 will have on the study going forward. We are monitoring the situation with site research nurse capacity, elective and urgent operations and radiology capacity. It will be some time before we see the long-term impact on recruitment to the study. For now, we ask that you do what you can on the study. We will be in contact on a regular basis to see how things are changing and will keep you informed.

New protocol version

Keep your eyes out for a new version of the study protocol coming soon. We have made a few changes relating to data collection, most notably to extend the period of the study in which the 90-day follow up forms will be collected. This is to ensure we get the most accurate safety data possible for study participants.



New study manual

V2.0 of the study manual can be found in the online Master Site File.

Progress update

As of 28/06/2020



48 sites are open



4073 people have been screened



64.9% of eligible patients have been randomised

Randomised patients are:

Elective		Urgent
78%		22%



30+ consultations have been recorded



33 trainees are registered to NIHR associate PI scheme



Total recruitment:

1,991 / 13,680

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3rd Investigators Meeting



Unfortunately the meeting scheduled for March 2020 was cancelled in light of COVID-19. We hope to be able to re-arrange this meeting to later this year, so that we can meet with you all in some capacity. Keep your eyes peeled for more information.

Questionnaires



The first sample of seven sites have completed administering questionnaires to their participants. 81% of baseline questionnaires were completed. We will be selecting our next sample of sites later this year.

The study is due to progress into **Phase 2** this Summer. We will let you know once this has been formally agreed by the study funder. It is a fantastic achievement that the study is in a strong position, many thanks to you all.

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