Open, multicentre, randomised controlled trial of cardiac output-guided haemodynamic therapy compared to usual care in patients undergoing emergency bowel surgery.

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Summary information for potential sites

Many thanks for your interest in the FLO-ELA trial. Please review the pre-trial protocol and this summary sheet and complete the Site Feasibility Form if you would like to participate.

Overview

FLO-ELA aims to give a definitive answer to the important question of whether perioperative cardiac output-guided haemodynamic therapy increases days alive and out of hospital in patients undergoing emergency laparotomy surgery. It is being funded by the NIHR Health Technology Assessment stream as part of a funding call supporting Efficient Study Designs. Because we need to study a large number of participants (3138) in a timely fashion (five years recruitment) we have set the study up to be simple, robust and pragmatic. In particular:

- All data on patients and their outcomes will be taken from the National Emergency Laparotomy Audit (NELA), and NHS datasets. We will add a small number of data fields to NELA to track the study intervention, but otherwise no additional data needs to be collected.
- Clinicians will help with study recruitment and will deliver the study intervention, as it is a treatment they are already familiar with. Trainee research networks are partners in the trial and will support its delivery.

As an NIHR-funded randomised trial we expect FLO-ELA to be adopted by the NIHR Portfolio as a Band 3 study. The host Clinical Research Network (CRN) has approved the support costs outlined below.

Delivering FLO-ELA locally

The care of emergency laparotomy patients involves a multidisciplinary team. The success of FLO-ELA is dependent on great support from a range of specialties, to help us recruit rapidly and to include the full range of patients going through this surgery. This will include patients needing surgery out of hours, and those who lack capacity to consent, although we recognise that these groups may be more challenging to recruit.

Experienced **consultant-level Principal Investigators (PIs)** will run the trial at each hospital, and may contribute to recruitment with consultant colleagues. **Research nurses** will screen, consent and randomise patients. They will also be responsible for ensuring the accuracy and completeness of data collection and monitoring compliance with the trial intervention and trial procedures. **Trainees** will contribute to screening, consent and randomisation and will help deliver the trial intervention alongside front line **consultant-level anaesthetists and intensivists.**

Each site should identify a lead from **anaesthesia, surgery and intensive care** who will promote and champion the trial within their clinical area and help overcome potential obstacles to study delivery. A **trainee lead** and **lead research nurse** should also be identified as these groups will play a key role in recruitment and delivery. The local team should agree a recruitment strategy that will work well for their setup. While some sites will be able to provide research nurse support for out-of-hours recruitment, in other centres this may be led by clinicians.

In order for FLO-ELA to succeed, each of the 100 sites involved should recruit on average **three or four** patients per month. Good compliance with the intervention protocol is also vital. Local leads will play a key role in ensuring this, and it will be monitored by local research nurses and the central FLO-ELA team. The first year of the FLO-ELA recruitment will act as an internal feasibility phase to confirm that sites are able to recruit enough patients and comply with the protocol. Sites with a very high protocol deviation rate (>10% of cases) during the feasibility phase will be excluded from the remainder of the trial.

Support for sites

- Sites will receive training on trial procedures and the clinical intervention before opening for recruitment.
- NELA data entry should continue as it is currently. Research nurses are not required to be present during the trial intervention period, although may give some assistance in the early trial period while familiarity with the FLO-ELA protocol develops.
- A per-site fee will cover the elements of research nurse time allocated to “research costs”, i.e. study set-up, randomisation and checking NELA data for completeness and protocol compliance. Time allocated to “NHS Support Costs” (screening and consenting patients) will be covered by local NIHR CRNs.
- Nearly all hospitals taking part in NELA already have access to cardiac output monitors. A number of manufacturers will provide consumables, and a monitor on loan where this is a barrier.
- An investigators’ meeting held at the end of the feasibility phase will help share best practices on delivering the trial.

Thank you for considering the FLO-ELA trial. Please see our website at www.floela.org or get in touch by emailing admin@floela.org if you need any further information.

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