

Peri-op Iron and EPO Intervention Study (POP-I)

Anaemia after major emergency surgery in older people is common and is associated with increased mortality, longer length of hospital stay and poorer quality of life.

There are no satisfactory trial data on the effectiveness of treatment of anaemia following emergency surgery. There is some evidence that intravenous iron and/or erythropoiesis stimulating agents may help improve outcomes.

The POP-I trial aims to recruit patients who are anaemic in the postoperative period following either emergency laparotomy or hip fracture. Participants who give consent will be assigned randomly into one of three study groups:

- 1: Usual care.
- 2: Iron by IV injection (Ferric derisomaltose, 100 mg/ml).
- 3: Iron by IV injection + an ESA injection (Darbepoetin alfa, 10–500 mcg/ml).

The Primary Outcome is 'Days at Home' up to 30 days after surgery (DAH30). We will also measure quality of life, safety, and costs associated with treatment.

Inclusion criteria for the study are:

- Age 60 or older.
- Mild to moderate anaemia. Hb 80–110g/l, measured postoperatively (day 2–10).
- Major non-elective surgery: *either* emergency laparotomy as defined by National Emergency Laparotomy Audit (NELA); *or* fragility hip fracture as defined by National Hip Fracture Database (NHFD).

Key exclusion criteria for the trial are:

- Acute uncontrolled infection as deemed by the treating clinician.
- No realistic prospect of survival.
- Use of intravenous iron / darbepoetin or other ESAs in last 30 days
- Direct contra-indications to iron / ESA treatment

We are looking for approximately 40 UK acute hospitals providing care for emergency laparotomy and/or hip fracture patients. We are planning to recruit 2400 participants. Sites of any size will be able to join if they perform surgery for patients with emergency laparotomy, hip fracture *or* both. The trial is funded by NIHR-HTA (NIHR133467) and is sponsored by the University of Nottingham.

To express an interest for your site to take part, please complete a site selection questionnaire available at our twitter page, @POP_I_Trial. The purpose of the questionnaire is to determine the suitability of your site for this trial. It is not an agreement to conduct the trial. We are interested in your honest assessment.

If you have any queries or would like to know more, you can contact the research team at POP-I@nottingham.ac.uk.