ITHRIVE: Iron and erythropoietin use in anaemic patients in the intensive care

ACTRN12621000595819

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Fiona Stanley Hospital
Enrollment	550 participants

Plain Language Summary

Many patients who spend time in an intensive care unit (ICU) develop anaemia — low levels of red blood cells — which can cause fatigue and slow recovery. Iron deficiency is a common cause, and erythropoietin is a hormone that stimulates red blood cell production. This trial tests whether giving intravenous iron together with erythropoietin can safely and effectively treat anaemia in ICU survivors who are well enough to be discharged from intensive care.

You may be eligible if you are an adult who has been in the ICU for more than 48 hours, are ready or almost ready to be transferred out of the ICU, and have a haemoglobin level below 100 g/L (indicating anaemia). People with active cancer, recent IV iron or erythropoietin treatment, known adverse reactions to these therapies, or who are pregnant are not eligible.

Participants are randomly assigned to receive either intravenous iron plus erythropoietin or a placebo, in addition to their usual care. The trial began as a small pilot study to test whether a larger trial is feasible, and is now expanding into a full clinical trial at multiple centres. Treating ICU-related anaemia effectively could speed up recovery and reduce the need for blood transfusions.

Key Eligibility Criteria

Inclusion (3)

- Adult patient who has required ICU-level care for more than 48 hours
- The treating clinician has determined that ICU discharge is appropriate or is likely to be appropriate in the next 24 hours
- Haemoglobin <100g/L on the most recent usual care measurement within the last 24 hours

Exclusion (13)

- Received IV iron therapy or ESA therapy in the last three months
- Active cancer+
- The treating clinician believes that trial participation is not in the best interests of the patient
- The treating clinician believes death during this hospital admission is inevitable
- Any history of adverse reaction to IV iron or ESA therapy, or therapies derived from mammalian cells

... and 8 more (see full listing online)

Locations (9 total)

Fiona Stanley Hospital - Murdoch, WA,VIC, Australia
Footscray Hospital - Footscray, WA,VIC, Australia
Sunshine Hospital - St Albans, WA,VIC, Australia
... and 6 more locations