

Iron infusion in iron-deficient patients undergoing surgery for colorectal cancer who are anaemic versus not anaemic in order to improve physical fitness as determined by exercise testing and a quality of life questionnaire.

ACTRN12616001219471

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| Status | RECRUITING |
| Phase | Phase 4 |
| Sponsor | Peter MacCallum Cancer Centre |
| Enrollment | 36 participants |

Plain Language Summary

This pilot study is looking at whether giving an iron infusion to patients with colorectal cancer who are iron-deficient before their surgery can improve their physical fitness. Patients who are iron-deficient but not severely anaemic will be randomly assigned to receive either an iron infusion or a saline (salt water) infusion, and their fitness will be measured before and after.

You may be eligible if:

- You are 18 years of age or older
- You have been diagnosed with colorectal cancer confirmed by biopsy
- You have low iron levels (ferritin below 100, or between 100–300 with low transferrin saturation)
- You are scheduled for colorectal surgery
- Your vitamin B12 and folate levels are normal

You may NOT be eligible if:

- Your anaemia is very severe (haemoglobin below 110 mg/dL and ferritin below 20)
- You have received iron therapy or a blood transfusion in the past 12 weeks
- You have had an allergic reaction to iron infusions before
- You have liver disease or a blood disorder like haemochromatosis
- You have a physical disability preventing exercise testing

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (6)

- Patients 18 years of age and older
- Patients with histologically confirmed colorectal cancer presenting to Peter MacCallum Cancer Centre, or Epworth Hospital (Richmond and Eastern campuses).
- Ferritin <100mcg/l or 100-300mcg/L and TSAT<20%
- Normal Serum Vitamin B12 and Folate levels
- Normal red cell folate and B12 levels
- ... and 1 more (see full listing online)

Exclusion (13)

- Hb (>130mg/dL male, or >120mg/dL female) & (either one of: Ferritin >300mcg/l, or Ferritin >100mcg/l and TSAT >20%)
- Marked Iron deficiency anaemia precluding randomization: Hb < 110 mg/dL & Ferritin <20 mcg/l
- Iron therapy contraindicated

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12616001219471>

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- Treatment with iron therapy or blood transfusion in the previous 12 weeks
 - Presentation for neoadjuvant CRT or Surgery within the study period
- ... and 8 more (see full listing online)

Locations (2 total)

Peter MacCallum Cancer Centre - Melbourne, VIC, Australia
Epworth Richmond - Richmond, VIC, Australia