ISRCTN61221573 https://doi.org/10.1186/ISRCTN61221573

A Prospective Randomised Controlled Trial of Iron Supplementation in Patients Scheduled for Colorectal Cancer Surgery

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 17/09/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0185146331

Study information

Scientific Title

Study objectives
To determine whether giving iron supplements to patients at the time of diagnosis of colorectal cancer increases or prevents the decrease in their haemoglobin levels and reduces allogeneic blood exposure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Cancer: Colorectal

Interventions
All patients seen in the outpatient clinic and scheduled for colorectal cancer surgery will be recruited. Patients will be randomised to receive iron supplements or nothing until 3 days prior to admission, so as not to interfere with bowel preparation. Blood tests including FBC, reticulocyte count, ferritin and plasma viscosity will be performed in clinic at 2 weeks and on the day of admission. During admission the details of the operation (type, surgeon, duration, blood loss) any transfusion and length of stay will be noted.

Intervention Type
Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)
Iron supplements

Primary outcome measure
To determine whether giving iron supplements to patients at the time of diagnosis of colorectal cancer increases, or prevents the decrease, in their haemoglobin levels, and reduces allogeneic blood exposure.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2001

Completion date
30/06/2004

Eligibility

Key inclusion criteria
All patients seen in clinic with a diagnosis of colorectal cancer and fit for surgery will be eligible.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/07/2001

Date of final enrolment
30/06/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
General Surgery Department
Plymouth
United Kingdom
PL6 8DH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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SW1A 2NL
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Plymouth Hospitals NHS Trust (UK), Own Account

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2007		Yes	No