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A trial to assess the efficacy of a new drug versus standard care for anaemia following colorectal cancer surgery

Submission date
11/01/2022

Recruitment status
No longer recruiting

Registration date
21/02/2022

Overall study status
Completed

Last Edited
14/07/2025

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Anaemia is a condition in which the number of red blood cells or the haemoglobin concentration within them is lower than normal. Haemoglobin is needed to carry oxygen and if you have too few or abnormal red blood cells, or not enough haemoglobin, there will be a decreased capacity of the blood to carry oxygen to the body's tissues. This results in symptoms such as fatigue, weakness, dizziness and shortness of breath, among others. Iron deficiency anaemia is caused by lack of iron, often because of blood loss or pregnancy.
Colorectal cancer is associated with iron deficiency anaemia in 40-60% of cases which can lead to poorer post-operative outcomes such as higher complication rates, increased length of stay and reduced survival. This study aims to evaluate whether the use of iron supplementation in the form of a new oral iron preparation - ferric maltol (Feraccru) could lead to a more sustained or improved response in haemoglobin if given after a colorectal cancer operation. This trial will run as a feasibility study to assess the proposed design.

Who can participate?
Anaemic colorectal cancer patients aged 18 years and above, treated with preoperative intravenous iron.

What does the study involve?
Participants will be randomly allocated to receive Ferric maltol (intervention group) or standard care (control group) postoperatively. Outcome measures will include a comparison of the change in blood indices, quality of life, allogenic red blood transfusion rates and postoperative complications between groups. Follow up will continue until the first postoperative outpatient visit at approximately 12 weeks following discharge.

What are the possible benefits and risks of participating?
The study may or may not have a direct benefit to recruited participants directly. It will be able to further our knowledge and hopefully benefit a great many patients with colorectal cancer in the future.
The participants will only be required to attend the hospital for one extra visit to consent and

where possible will be arranged to coincide with existing appointments. All other procedures are carried out when the participant attends their routine visits as per the normal clinical pathway.

Where is the study run from?
The Royal Wolverhampton NHS Trust (UK)

When is the study starting and how long is it expected to run for?
January 2022 to May 2025

Who is funding the study?
Norgine Ltd (UK)

Who is the main contact?
Nuha Yassin, nuha.yassin@nhs.net

Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number
2021-006004-32

IRAS number
1003910

ClinicalTrials.gov number
NCT05177484

Secondary identifying numbers
2021GAS120, IRAS 1003910, CPMS 52260

Study information

Scientific Title
An open-label randomised trial to assess the efficacy of post-operative ferric maltol vs standard care for anaemia following colorectal cancer surgery

Acronym
PiCoC

Study objectives
To determine the feasibility of a phase IV open label, controlled multi-centre randomised trial of oral ferric maltol versus standard care postoperatively for colorectal cancer patients who have been treated with preoperative intravenous iron for anaemia. Feasibility measures will include:
• Eligible patients from screening
• Study exclusion
• Acceptability of recruitment
• Study retention

• To investigate whether the use of ferric maltol could improve the postoperative quality of life of patients after colorectal cancer surgery compared to standard care.
• To calculate the change in postoperative haemoglobin and haematinics in response to ferric maltol compared to standard care.
• To compare postoperative allogenic red blood cell transfusion rates in patients receiving ferric maltol or standard care

• To review the tolerability of ferric maltol for the treatment of postoperative colorectal cancer patients
• To compare length of stay and complication rates in patients receiving ferric maltol or standard care postoperatively.
• To assess for immunological and metabolomic peri-operative differences between patients receiving ferric maltol preparations and standard care

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/05/2022, Health and Care Research Wales (Castlebridge 4, 15-19 Cowbridge Road, Cardiff, CF11 9AB, United Kingdom; +44 (0)1686 252101; Wales.REC2@wales.nhs.uk), ref: 22/WA/0035

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Anaemia with colorectal cancer

Interventions
This study will be comparing the effect of postoperative oral ferric maltol (intervention group) to standard care (control group), in patients with colorectal adenocarcinoma who have received pre-operative intravenous iron for anaemia. Each patient will be expected to participate for a period of 10 to 20 weeks, depending on the time between their diagnosis and the planned operation date. After consenting to participate baseline data will be noted. Patients will be asked to complete the 3 quality of life questionnaires and they will have their blood taken including a full blood count, haematinics (including iron, ferritin, transferrin and transferrin saturation) urea and electrolytes, liver function tests and erythropoietin. The patients may be asked to give other samples of faeces, urine, saliva or sweat. Once the surgical procedure has been performed, tissue samples from the resected bowel may be obtained for analysis. The participant is next reviewed when they are admitted on the morning of the operation. Blood tests and the quality of life questionnaires will be repeated. Preoperatively patients will undergo randomisation to one of the two study arms via an online tool. After operation the

participants haemoglobin will be checked on day 2 of their recovery. If, at this point, postoperative anaemia is confirmed they will enter into their allocated study arm. The intervention group will commence a course of oral ferric maltol and the control group will receive standard care. All patients will have blood tests checked again at day 3 and day 5 postoperatively if they remain as an inpatient. If they are found to be anaemic on either of these two blood tests they will, at this stage, enter their allocated treatment pathway. If a patient shows no evidence of anaemia on either day 2, 3 or 5 blood tests they will be withdrawn from the study. The patients may be asked to give other samples of faeces, urine, saliva or sweat at days 2, 3 or 5 along with the blood tests. Patients will continue treatment according to their randomisation allocation until 12 weeks after the operation, at which point the patient attends a routine surgical outpatient follow-up clinic. During the outpatient visit the participants will undergo their final blood and body fluid testing and questionnaire completion.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Ferric maltol

Primary outcome measure
Feasibility outcomes:
1. Eligible patients from screening - recorded as the number of eligible patients for the study until the end of recruitment at 18 months
2. Study exclusion - patients who are below the age of 18, those on chemoradiotherapy prior to surgery and other potential causes for anaemia apart from the colorectal cancer
3. Acceptability of recruitment - Recruitment rate recorded as the number of eligible participant who consent to participate in the study by 18 months
4. Study retention - Attrition rate recorded as the number of participants who consent to participate that remain in the study until the end of follow up at 21 months

Secondary outcome measures
Measured using patient records unless otherwise noted:
1. Levels of haemoglobin and haematinic markers (full blood count, ferritin, iron, transferrin, and transferrin saturation). Immunological and metabolomic markers will also be assessed. These will be measured at a point preoperatively before intravenous iron treatment, on the day of surgery and at defined time points postoperatively during the administration of oral ferric maltol or during standard care
2. Side-effects and reactions to ferric maltol administration
3. Peri- and post-operative morbidity and mortality
4. Post-operative complications
5. Post-operative length of stay
6. Post-operative allogenic blood transfusion.
7. Quality of life as determined by the SF36, EQ-5D and FACT-An questionnaires.

Overall study start date
06/01/2022

Completion date

29/05/2025

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study.
2. Male or Female, aged 18+ years.
3. Diagnosed with histologically or radiologically diagnosed colorectal adenocarcinoma.
4. Anaemic at point of diagnosis of colorectal adenocarcinoma (Defined as haemoglobin 10 g/L below WHO criteria: 120 g/L for males and 110 g/L for females, to account for a 10% fluctuation in Hb)
5. Undergoing surgery for colorectal cancer with curative intent.
6. Date of planned surgery is ≥14 days from date of planned initiation of recruitment.
7. Able (in the investigators opinion) and willing to comply with all study requirements.
8. Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
42

Key exclusion criteria
1. Patients with mental health issues or learning disabilities resulting in their inability to consent to the study
2. Patients who do not have a histological diagnosis of colorectal adenocarcinoma
3. Female participants who are pregnant, lactating or planning a pregnancy during the course of the study.
4. Patients with evidence of iron overload or disturbances in utilisation of iron as stated in the product SPC.
5. Previous gastric, small bowel or colorectal surgery (where ≥50% of stomach or terminal ileum has been resected)
6. Chemotherapeutic treatment within the last 4 weeks.
7. Known previous anaemia not attributable to colorectal carcinoma (i.e. anaemia in patients with well established, inflammatory disorders)
8. Known haematological disease.
9. Features necessitating urgent surgery (e.g. obstructive symptoms).

10. Previous allergy to intravenous or oral iron or related iron products.
11. Patients who are unable to consent.
12. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study.
13. Participants who have participated in another research study involving an investigational product in the past 12 weeks
14. Confirmed liver or lung metastases

Date of first enrolment
15/02/2022

Date of final enrolment
06/12/2023

Locations

Countries of recruitment
United Kingdom

Study participating centre
New Cross Hospital Royal Wolverhampton
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Sponsor information

Organisation
The Royal Wolverhampton NHS Trust

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Sponsor type

Hospital/treatment centre

Website
https://www.royalwolverhampton.nhs.uk/

ROR
https://ror.org/05pjd0m90

Funder(s)

Funder type
Industry

Funder Name
Norgine Ltd

Results and Publications

Publication and dissemination plan
Peer reviewed scientific journals
Conference presentation
Publication on website
Submission to regulatory authorities

Intention to publish date
01/11/2025

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 0.5	30/05/2022	26/09/2023	No	No
Other unpublished results	version 3	04/07/2025	14/07/2025	No	No
Protocol file		27/10/2023	14/07/2025	No	No