ISRCTN48118194 https://doi.org/10.1186/ISRCTN48118194

Effectiveness of iron supplementation in the non-anaemic iron deficient patient population undergoing arthroplasty

Submission date
31/10/2018

Recruitment status
No longer recruiting

Registration date
04/02/2019

Overall study status
Completed

Last Edited
04/02/2019

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Anaemia is a condition where the body does not have as much haemoglobin or as many red blood cells as it needs. An international consensus statement suggesting the need to treat preoperative anaemia was published in 2016. In this statement, anaemia and non-anaemic iron deficiency (where the body does not have as much iron as it needs) were identified as patient groups that would benefit from the introduction of pre-operative anaemia screening, assessment and treatment. They suggested that patients with low iron levels, with or without anaemia, should be given iron supplementation to enable them to recover from surgery. The benefits of this has been demonstrated in the anaemic population, whereas there is limited research into this for the non-anaemic iron deficient population.
The aim of this trial is to analyse the effect of iron supplementation in non-anaemic iron deficient patients undergoing lower limb arthroplasty.

Who can participate?
Adult non-anaemic iron deficient patients undergoing hip or knee arthroplasty

What does the study involve?
Participants will be randomly allocated to the intervention group or the control group. The intervention group will receive iron supplementation for six months, covering the pre-operative and post-operative phases of their care. They will receive supplementation for 4 weeks prior to their surgery. The control group will receive care as usual. All participants will have blood tests every 4 weeks throughout the trial, along with 3 weeks after surgery. They will also be asked to complete questionnaires 4 weeks after surgery and 3 months after surgery.

What are the possible benefits and risks of participating?
The possible benefit to participants in the intervention group is that iron supplementation may be effective in improving their recovery from surgery. There are no known benefits for the control group. The results of this study may benefit future patients if the treatment is proven to be effective.
Possible risks of participating include the standard risks associated with blood samples and

gastrointestinal symptoms of oral iron supplementation. These symptoms include abdominal pain, constipation, diarrhoea, nausea and dark stools.

Where is the study run from?
Northumbria Healthcare NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
May 2018 to May 2020

Who is funding the study?
SALUS Haus (Germany)

Who is the main contact?
Mike Reed
mike.reed@nhs.net

Contact information

Type(s)
Public

Contact name
Prof Mike Reed

ORCID ID
http://orcid.org/0000-0002-6309-2710

Contact details
Northumbria Healthcare NHS Trust
Wansbeck General Hospital
Woodhorn Lane
Northumberland
United Kingdom
NE63 9JJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ISIDA Protocol 1.0

Study information

Scientific Title
ISIDA: Iron Supplementation for non-anaemic Iron Deficiency before lower limb Arthroplasty

Acronym
ISIDA

Study objectives
Non-anaemic iron deficient patients undergoing lower limb arthroplasty will benefit from iron supplementation to improve their haemoglobin recovery post surgery, whilst improving anaemia symptoms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
HRA and Health and Care Research Wales (HCRW), 21/12/2018, ref: 18/NE/0371

Study design
Interventional single centre two-armed randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Non-anaemic iron deficiency

Interventions
Randomisation will be performed using simple randomisation with the algorithm from www.randomization.com. Patients will be randomised to receive either the intervention or the control.
The intervention arm will receive oral iron supplementation with Foradix mit Eisen (36.8 mg oral iron daily) for 6 months from the point of inclusion, which includes the preoperative and postoperative phases of care.
The control arm will receive no intervention and will have care as usual.
All patients will have blood sampling at 3 weeks post surgery, and at 4 weekly intervals during the trial to test for haemoglobin, C-reactive protein and ferritin levels.
From enrollment in the trial, participants will have blood samples taken every 4 weeks up to 6 months, and will be asked to complete questionnaires 4 weeks after surgery and 3 months after surgery.

Intervention Type

Supplement

Primary outcome measure
Haemoglobin recovery, assessed using blood samples taken at the baseline and 3 weeks after surgery

Secondary outcome measures
1. Length of hospital stay, determined using the patient administration system throughout the study
2. Transfusion rate and number of units transfused, assessed using the transfusion database after 30 days
3. Adverse events (including all cause morbidity and mortality, assessed using patient clinical notes after 30 and 90 days
4. Full blood count (FBC), C-reactive protein (CRP) and ferritin levels, assessed using a blood test every 4 weeks throughout the 6 month trial
5. Readmission within 30 days of surgery, assessed using the patient administration system up to 30 days after surgery
6. Inpatient deep vein thrombosis (DVT) or pulmonary embolism (PE) within 30 days of surgery, assessed using patient clinical notes up to 30 days after surgery
7. Pneumonia within 30 days of surgery, assessed using patient clinical notes up to 30 days after surgery
8. Cerebrovascular incident within 30 days of surgery, assessed using patient clinical notes up to 30 days after surgery
9. Myocardial infarction within 30 days, assessed using patient clinical notes up to 30 days after surgery
10. Fatigue, assessed using the FACIT Fatigue Scale 4 weeks after surgery
11. Quality of life, assessed using the EQ-5D-5L questionnaire 3 months after surgery

Overall study start date
01/05/2018

Completion date
31/05/2020

Eligibility

Key inclusion criteria
1. Undergoing primary knee or hip replacement surgery
2. Aged over 18 years
3. Non-anaemic iron deficiency, diagnosed using the following criteria:
3.1. Haemoglobin levels >12 for women and >13 for men
3.2. Ferritin levels <50
4. Not already be taking regular oral iron
5. Provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
188 research participants, 94 in each trial arm

Key exclusion criteria
1. Lack capacity to consent to inclusion in the trial
2. Refusal to participate
3. Known allergy/intolerance to any iron supplementation treatment option
4. Pregnancy
5. Listed for surgery within four weeks of commencing iron supplementation

Date of first enrolment
18/04/2019

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northumbria Healthcare NHS Foundation Trust
Research and Development
North Tyneside General Hospital
Rake Lane
North Shields
Northumberland
United Kingdom
NE29 8NH

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

Sponsor details

Research and Development Department
North Tyneside General Hospital
Rake lane
North Shields
England
United Kingdom
NE29 8NH

Sponsor type
Hospital/treatment centre

Website
www.northumbria.nhs.uk

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Industry

Funder Name
SALUS Haus (Germany)

Results and Publications

Publication and dissemination plan
Publication will be sought in an international journal on the primary and secondary outcome data and in a PhD Thesis. Outcomes will be shared at scientific meetings

Intention to publish date
01/03/2021

Individual participant data (IPD) sharing plan
Anonymised raw data from the primary and secondary outcomes will become available after publication. This may be shared with researchers for future research purposes and access will be assessed on an individual basis. Patients have provided consent for anonymised data sharing for the purpose of future research.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

HRA research summary	28/06/2023	No	No