

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

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<b>Registration date</b> 04/02/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/02/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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## Contact information

### Type(s)

Public

### Contact name

Prof Mike Reed

### ORCID ID

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### Contact details

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## Additional identifiers

### Protocol serial number

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

### **Study type(s)**

Quality of life

### **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](http://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(s)**

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

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **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**

United Kingdom

England

**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

**ROR**

<https://ror.org/01gfeyd95>

## Funder(s)

**Funder type**

Industry

**Funder Name**

SALUS Haus (Germany)

## Results and Publications

## 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?
<a href="#">HRA research summary</a>			28/06/2023	No	No