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Does increasing lean red meat intake impact iron status in physically-active women?

Submission date
15/05/2023

Recruitment status
No longer recruiting

Registration date
16/05/2023

Overall study status
Completed

Last Edited
21/10/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Background and study aims
Female athletes and active adult females participating in high volumes of exercise are at increased risk of compromised iron status due to heightened iron losses through menstruation and exercise-induced mechanisms associated with exercise training. Oral iron supplementation is commonly used in the prevention or/and treatment of iron deficiency but has been criticised because of the side effects such as constipation and increased risk of iron toxicity associated with the use of supplements. The prescription of an iron-rich and/or heme-iron-based diet (from meat) can assist in improving and maintaining iron status in females, and this study is needed to explore this paradigm. Therefore, this project will investigate the effects of the consumption of lean red meat on iron status in iron deficient physically-active females in comparison to a habitual diet or an oral iron supplement.

Who can participate?
Physically-active females aged 18 to 40 who are defined as iron deficient without anaemia

What does the study involve?
Participants will be randomised into one of the three groups for the 12 week intervention: CON - habitual diet with the provision of oral placebo (gelatine capsules) to be consumed on alternate days for 12 weeks; SUPP - habitual diet with the provision of oral iron supplement to be consumed on alternate days for 12 weeks; MEAT - habitual diet with the provision of portions of lean red meat to be consumed for dinner on alternates days for 12 weeks.

What are the possible benefits and risks of participating?
Direct benefits will include each participant receiving information on her iron status, nutrient intakes, and measures of body composition. At the end of the study, each participant will receive a document that includes her results from all four visits, and accurate advice and information on all aspects of diet to do with improving iron status.

Where is the study run from?
Dublin City University (Ireland)

When is the study starting and how long is it expected to run for?
January 2022 to December 2024

Who is funding the study?
Enterprise Ireland

Who is the main contact?
Dr Brendan Egan, brendan.egan@dcu.ie

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
DCUREC2022_120

Study information

Scientific Title
Effects of increased consumption of lean red meat on iron status in iron-deficient physically-active females

Acronym
RMIDNA

Study objectives
Regular intake of lean red meat can improve iron status in iron-deficient non-anaemic physically-active females

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/03/2023, Dublin City University Research Ethics Committee (DCU Glasnevin Campus, Invent Building, DCU, Glasnevin, Dublin 9; Republic of Ireland; +353 1 7008000; research@dcu.ie), ref: DCUREC/2022/120

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Fitness/sport facility, University/medical school/dental school

Study type(s)
Quality of life, Treatment, Efficacy

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
Iron deficiency without anemia

Interventions
48 physically-active iron-deficient non-anaemic female participants (per trial arm: n=16; age 18 to 40 years, currently active for 4 exercise sessions per week lasting more than 30 minutes each at high intensity, or more 60 minutes at moderate intensity, or a combination thereof moderate and high-intensity sessions) will be randomly assigned to either a control group or a 12-week intervention of Control diet (their habitual diet), Supplement (provision of oral iron supplements), and Meat (provision of lean red meat).

The participants will be pre-screened (Phase I) for their level of physical activity (IPAQ Questionnaire), and fatigue risk using an online Low Energy Availability in Females Questionnaire (LEAF) and subjective ratings of fatigue (POMS). Those identified at risk then moving forward to blood sample (in the follicular phase of their menstrual cycle on day 3 to day 5 of full flow) for analysis of the various markers of iron status (baseline serum blood sample) and habitual dietary iron intake using a 4-day portion estimate food diary.

If fulfilling the inclusion criteria for iron status, participants will be matched for baseline iron status and habitual dietary iron intake before block randomisation into one of the three groups

for the 12 week intervention (Phase II, starting on day 6 to 8 from the first day of full flow).
•CON: habitual diet with the provision of oral placebo (gelatine capsules) to be consumed on alternate days for 12 weeks.
•SUPP: habitual diet with the provision of oral iron supplement providing 325 mg ferrous sulfate (an additional 105 mg of elemental iron) to be consumed on alternate days for 12 weeks.
•MEAT: habitual diet with the provision of portions of lean red meat (170 g uncooked = ~ 120 g serving of cooked beef in the form of lean mince (~5% fat), stewing beef, or steaks; ~3 to 5 mg additional iron) to be consumed for dinner (at or after 6 PM) on alternates days for 12 weeks.

Participants will be assessed before (0 week), during (4 and 8 weeks) and after (12 weeks) the intervention period specifically for: Iron status from a venous blood sample; Body composition will be measured by bioelectrical spectroscopy (SOZO, Impedimed) and skinfold measurement by callipers; Subjective ratings of fatigue and mood states (POMS); Dietary habits will be assessed by a 4 day portion estimate food diary with analysis by commercial dietary analysis software (Nutritics).

The discordance between the daily iron intakes of SUPP and MEAT is intentional and acknowledged but represents a pragmatic approach. SUPP reflects recent sports nutrition guidelines for iron supplementation in female athletes and MEAT reflects the approximate intake from a previous study of meat and iron status in exercising females as well as an average portion described by The Health Service Executive (HSE) of Ireland Food Guidelines.

Intervention Type
Mixed

Primary outcome measure
Iron status: serum iron, serum transferrin receptor, transferrin, transferrin saturation, and ferritin measures from which total iron binding capacity and serum transferrin receptor/log ferritin ratio will be calculated from a venous blood sample at baseline, 4, 8 and after 12 weeks.

Secondary outcome measures
1. Subjective ratings of fatigue: Measured using an online Low Energy Availability in Females Questionnaire (LEAF) and subjective ratings of fatigue and mood state (Profile of Mood States-POMS Questionnaire) at 0, 4, 8 and after 12 weeks;
2. Body composition by bioelectrical spectroscopy (SOZO, Impedimed) and skinfold measurement by callipers at 0, 4, 8 and after 12 weeks;
3. Dietary iron intake will be assessed by a 4-day food diary with analysis by commercial dietary analysis software (Nutritics) at 0, 4, 8 and after 12 weeks;
4. Full blood count including hemoglobin measured in blood samples at 0, 4, 8 and after 12 weeks;
5. Types of the intensity of physical activity and sitting time that people do as part of their daily lives to estimate the total physical activity in MET-min/week and time spent sitting, the International Physical Activity Questionnaire (IPAQ), at 0, 4, 8 and after 12 weeks.
6. Training log recording session duration and session RPE throughout the 12 week period.

Overall study start date
03/01/2022

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Phase I
1. Female;
2. Aged 18 to 40 years;
3. Physically active defined as currently active for not less than 4 exercise sessions per week lasting more than 30 minutes each at high intensity, or more than 60 minutes at moderate intensity, or a combination thereof moderate and high intensity sessions;

Phase II
4. Participants fulfilling the inclusion criteria for status as iron deficient without anaemia i.e. a haemoglobin concentration not less than 12.0 g/dL i.e. non-anaemic, and either serum ferritin = or more than 12 and <35µg/L, or transferrin saturation <16%, or both, combined with habitual dietary iron intake of less than the current estimated average requirement (EAR) i.e. <11.4 mg /day, will be eligible to move forward into Phase II.

Participant type(s)
Healthy volunteer, Other

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex
Female

Target number of participants
48

Total final enrolment
40

Key exclusion criteria
1. Male;
2. Individuals under the age of 18 and over 40 years of age;
3. Individuals with normal iron status (Ferritin >35 µg/L and haemoglobin = or more than 12 g /dL); Individuals with anaemia (haemoglobin <12 g/dL for females);
4. Individuals who present with neuromuscular, chronic, and metabolic diseases and carriers of high-risk blood-borne diseases;
5. Individuals currently on an energy-restricted diet;
6. Individuals currently supplementing with iron or vitamin C supplements;
7. Individuals currently practising a dietary restriction as vegetarian, vegan, ketogenic or Low

carbohydrate diet (defined as CHO intake of <130 g/day);
8. Habitual dietary iron intake in accordance to the current estimated average requirement (EAR) i.e. = or more than 11.4 mg/day

Date of first enrolment
01/06/2023

Date of final enrolment
31/01/2024

Locations

Countries of recruitment
Ireland

Study participating centre
Dublin City University
Collins Avenue
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Ireland
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Sponsor information

Organisation
Dublin City University

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Sponsor type
University/education

Website
http://www.dcu.ie/

ROR
https://ror.org/04a1a1e81

Funder(s)

Funder type
Government

Funder Name
Enterprise Ireland

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Publication and dissemination plan
Results may be disseminated in academic journal publications and presented at scientific conferences, but never as an individual's identifiable data. At major intervals (e.g when a phase of the project is finished, or a paper is published), participants will be informed via email. Emails will include a lay description of what findings were published and the research team's interpretation of these findings. Participants may contact the research team should they have interest in the progress of the project, and will be given access to publication manuscripts or research posters/slides upon request. Feedback on the outcome of the pre-screening process (assessment of iron status) will be provided to each individual participant for their own data, as will feedback on the outcomes of the study itself for each individual participant for their own data.

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan
The data sets generated during and/or analysed during the current study will be available on request from brendan.egan@dcu.ie

IPD sharing plan summary
Available on request