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How the menstrual cycle affects energy use during exercise

Submission date
14/04/2025

Recruitment status
No longer recruiting

Registration date
11/06/2025

Overall study status
Completed

Last Edited
11/06/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
In recent years, the activities of female athletes have been increasing. However, research has tended to focus on the male population, and less is known about the effects of the menstrual cycle on energy use during exercise. During exercise, the human body uses ingested food to provide energy to the muscles used. This food is broken down and stored as glycogen or fat in the liver and muscles, ready to supply energy when needed. The amount of glycogen and fats used during exercise can influence performance, fatigue and health outcomes and understanding these dynamics is foundational in sports medicine and metabolic disorders (e.g. diabetes). This study aims to investigate how variations in hormones throughout the menstrual cycle impact energy use in the muscle and liver to provide foundational knowledge for future research and public health policies.

Who can participate?
Active healthy female participants aged 18 - 35 who have regular menstrual cycle (25 - 38 days) and undertake regular moderate exercise (e.g. 45 minutes brisk walking or light running 3 days per week).

What does the study involve?
After an initial set-up visit (outlined below), participants will attend the test centre on 4 separate occasions, one week apart, each after a standardized breakfast. Blood samples will be taken to determine hormonal levels, and ovulation kits will be provided so that the menstruation status of each visit is precisely known. In an initial set-up visit (before the main 4-week study), participants will undertake an exercise test on a stationary exercise bike to determine the intensity needed for a personalised exercise at 70% of their maximum exercise capacity (called 70% VO2 max). Following this, for each of the 4 weekly visits, participants will undergo a 45-minute cycle exercise where the researcher will maintain the intensity at their pre-determined 70% VO2 max. Before and after each cycle of exercise, participants will undergo a 15-30 minute MRI scan, and blood samples will be taken. Data from the MRI scan will be used to determine glycogen concentrations in the liver and muscle, and blood analysis will be used to determine glucose, lipid and lactate levels. The difference in the before- and after-exercise measurement will be used to determine how much of each metabolite has been used during exercise.

What are the possible benefits and risks of participating?
This study is a basic science physiological study, and so there are no direct health benefits to participants. However, the measurements will provide crucial data for future research. The risks in taking part are minimal as there are no experimental interventions. There are some small risks associated with MRI (such as heating and noise) which are outlined in detail in the participant information sheet and carefully mitigated against in the study. Similarly, there are small risks associated with taking a blood sample.

Where is the study run from?
Queen's Medical Centre, Nottingham

When is the study starting and how long is it expected to run for?
September 2021 to September 2023

Who is funding the study?
NIHR Nottingham Biomedical Research Centre

Who is the main contact?
Dr. Stephen Bawden, stephen.bawden1@nottingham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Stephen Bawden

ORCID ID
https://orcid.org/0000-0002-5157-3269

Contact details
Clinical Imaging Facility,
ILS2 College of Medicine
Swansea
United Kingdom
SA2 8PP
+44 (0)1792703729
stephen.bawden1@nottingham.ac.uk

Type(s)
Principal investigator

Contact name
Prof Guruprasad Aithal

ORCID ID
https://orcid.org/0000-0003-3924-4830

Contact details

Room W/E 1418 E Floor, West Block
Queen's Medical Centre
Nottingham
United Kingdom
NG7 2UH
+44 (0)115 823 1031
guru.aithal@nottingham.ac.uk

Type(s)
Public

Contact name
Mr Henry Bowler

Contact details
Sir Peter Mansfield Imaging Centre, Building 18,
University Park Campus
Nottingham
United Kingdom
NG72QX
+44 (0)115 9514747
Henry.Bowler@nottingham.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR Nottingham Biomedical Research Centre BRC-1215–20003

Study information

Scientific Title
Influence of the menstrual cycle on muscle and liver glycogen and circulating substrates during exercise in healthy women

Acronym
IMCOM

Study objectives
Variations in ovarian hormones throughout the menstrual cycle significantly affect glycogen utilisation in the liver and muscle during exercise, as measured by 13C-MRS, with distinct differences observed across the early follicular phase (E-FP), late follicular phase (L-FP), early luteal (E-LP) and late luteal phase (L-LP).

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 24/09/2021, Faculty of Medicine and Health Sciences Research Ethics Committee (Room E41, E floor, Medical School, Queens Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG72UH, United Kingdom; +44 (0)115 9515 559; FMHS-ResearchEthics@nottingham.ac.uk), ref: FMHS 323-0821

Study design
Single-centre observational study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Natural changes in metabolic responses to exercise over the menstrual cycle.

Interventions
A single-centre observational study where the metabolic responses to exercise will be measured in healthy female participants at 4 weekly timepoints throughout their menstrual cycle.

Healthy active females (aged 18-35) with regular menstrual cycles and no hormonal contraceptives will attend the test centre after a standardized breakfast and partake in a 45-minute cycle exercise at 70% VO2 max. Liver and muscle glycogen levels will be measured using 13C Magnetic Resonance Spectroscopy (MRS) before and after exercise. Blood samples will also be taken alongside MRS to measure sex hormones, glucose, lipids and lactate.

Intervention Type
Other

Primary outcome(s)
Exercise-induced changes in liver glycogen concentrations (difference between before and after 45-minute cycle exercise) measured using 13C Magnetic Resonance Spectroscopy (MRS) on 4 separate occasions, one week apart.

Key secondary outcome(s))
1. Exercise-induced changes in muscle glycogen concentrations (difference between before and after 45-minute cycle exercise) measured using 13C MRS at 4 separate occasions, one week apart.
2. Blood metabolites (glucose, lactate, lipids) and hormones (estradiol, progesterone, luteinizing hormone and follicular stimulating hormone) measured before and after a 45-minute cycle exercise using blood assays on 4 separate occasions, one week apart.

Completion date
01/09/2023

Eligibility

Key inclusion criteria
1. Female
2. Age 18 - 35 years
3. Regular menstrual cycle (every 25 - 38 days)
4. Nulliparous
5. Habitual exercise - 45 minutes of moderate exercise (brisk walking or jogging), minimum 3 days per week

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
Female

Total final enrolment
10

Key exclusion criteria
1. A history of smoking or chronic diseases
2. Use of oral contraceptives or other hormone medications for at least 6 months prior
3. Pregnancy or lactation
4. Pearning difficulties or cognitive impairments or social problems or substance abuse, or mental illness, which would make it difficult to complete the protocol

Date of first enrolment
01/09/2021

Date of final enrolment
01/09/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Sir Peter Mansfield Imaging Centre
Building 18,
University of Nottingham,
University Park
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Nottingham Biomedical Research Centre

Alternative Name(s)
Nottingham Biomedical Research Centre, Nottingham Biomedical Research Centre - NIHR, NIHR Nottingham BRC, BRC, NIHR NBRC

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be available upon request from Dr. Stephen Bawden, stephen.bawden1@nottingham.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files		05/08/2021	16/04/2025	No	No
Participant information sheet	version 1.0	16/08/2021	16/04/2025	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 1.1	17/09/2021	16/04/2025	No	No