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Examining the clinical effectiveness, feasibility and acceptability of intra-apheresis cycling for peripheral blood stem cell donations

Submission date
19/05/2026

Recruitment status
Recruiting

Registration date
20/05/2026

Overall study status
Ongoing

Last Edited
28/07/2026

Condition category
Cancer

[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
Every year, more than 90,000 people around the world receive stem cell transplants to treat illnesses such as myeloma, a type of blood cancer. Stem cells need to be collected from the donor's blood prior to transplant, and this process takes at least three hours and sometimes has to be repeated over several hospital visits to collect enough cells. As well as the time burden, low cell numbers and complications after transplant still happen, highlighting a clinical need to develop novel approaches.

In earlier work, the research team found that attaching pedals to the end of a chair and performing light cycling spaced out over 3 hours increased the number of stem cells and white blood cells important for a successful transplant. The team now aim to find out whether people with myeloma and volunteer matched donors can comfortably undertake brief periods of light cycling during their donation, and whether this helps collect more cells and increase the success of the transplant. The findings will help plan for the future use of this concept in a hospital setting to improve stem cell collections for people with myeloma, volunteer donors and other conditions.

Who can participate?
Patients with myeloma who have a scheduled blood stem cell collection and volunteer matched donors who have a scheduled blood stem cell collection.

What does the study involve?
After consent and screening, donors will be randomly placed into either their standard stem cell donation group or a cycling group (plus standard donation). Those in the cycling group will pedal lightly for 4 minutes every 20 minutes during their stem cell donation. Blood samples will be taken from both groups before and afterwards, but this will be separate and not affect the stem cells collected for transplant.

What are the possible benefits and risks of participating?
Benefits: The research team can provide you with a report of your activity levels measured

during the study. By taking part, you will help them to evaluate the impact of a novel non-drug-based protocol aiming to directly improve clinical care for people with myeloma and other illnesses. Once the study has finished, participants will be provided with information on the findings and plans for future projects.

Risks:
Peripheral Blood Stem Cell Collection
Participants will be informed by their medical team of the risks associated with undergoing a peripheral blood stem cell collection.

Blood Samples
For the research blood samples, the team will need to briefly insert a small needle into a vein in the participant's arm twice during the stem cell collection session (before and after). As far as discomfort is concerned, there might be a small sting with insertion, but otherwise, these procedures are not usually painful. There is a very small risk of infection and bruising at the site of insertion. This risk will be much reduced using trained medical staff and good procedures. The amount of blood taken each time (40mL) is equivalent to less than 3 teaspoons. It is safe to lose this amount of blood during the stem cell collection session, and most importantly, it will not impact the quantity/quality of blood cells being reinfused into the body.

Fatigue During Exercise
The exercise performed is light, and so the chances of any risks are extremely low. Participants may feel a bit tired while they’re cycling, but this is normal and will be short-lived. They should fully recover within hours of the process. There is a very small risk of unexpected heart problems during any type of exercise, but this is an extremely low risk. Although specific figures are not available for people with myeloma, the risk of a serious heart problem in adults without heart disease only happens once every 400,000 – 800,000 hours of vigorous exercise. Even in patients with heart conditions, who are recognised as high risk, the likelihood is still extremely small (1 death every 176,000 hours of vigorous exercise). Participants can stop exercising at any time if they start to feel uncomfortable.

Where is the study run from?
The Centre for Clinical Haematology (Birmingham Centre for Cellular Therapy and Transplant) at the Queen Elizabeth Hospital, Birmingham, UK.

When is the study starting and how long is it expected to run for?
June 2026 to March 2027.

Who is funding the study?
The Academy of Medical Sciences, UK.

Who is the main contact?
Phoebe Cox, stemex@contacts.bham.ac.uk

Contact information

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Public

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Additional identifiers

Integrated Research Application System (IRAS)
326850

Central Portfolio Management System (CPMS)

70257

Academy of Medical Sciences Grant Code
SBF0010\1201

Study information

Scientific Title
Harvesting STEM cells through intra-apheresis EXercise

Acronym
STEM-Ex

Study objectives
The primary aim of this project is to examine the clinical effectiveness of undertaking intermittent periods of cycling (intra-apheresis cycling) during peripheral blood stem cell donations vs. standard of care in people with myeloma and volunteer, matched donors.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/02/2026, Health and Social Care Research Ethics Committee A (HSC REC A) (Office for Research Ethics Committees Northern Ireland (ORECNI) Business Services Organisation Unit 4, Lissue Industrial Estate West, Lisburn, BT28 2RF, United Kingdom; +44 028 9536 1400; RECA@hscni.net), ref: 26-NI-0009

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Supportive care

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple myeloma

Interventions

Hypothesis

This project will be conducted as a pilot trial to address key uncertainties in designing a definitive randomised controlled trial, which will test the hypothesis that cycling during a stem cell collection elicits a higher stem cell dose and speeds up collection time, compared to standard of care (control).

Study Sample Size

Approximately 200 autologous donations for myeloma will take place at the Birmingham Centre for Cellular Therapy and Transplant over the planned 15-month data collection period. In line with our patient engagement, a recruitment rate of 25% is sufficient to fulfil the feasibility objectives of this study. Anticipating a 50% recruitment rate for allogeneic donors, the study will recruit 20 healthy donors for equal randomisation, using the web-based platform called Sealed Envelope, into the cycling or control groups.

Study Design and Methodology

The design and methodology outlined below are the same for both myeloma (patients) and healthy donors:

1. Before Study (30-minute time commitment)

As part of the participants' routine clinical appointments, as they prepare for the stem cell collection, the procedures outlined below will be conducted:

1.1. Eligibility

An assessment of eligibility for the study involves asking some routine questions.

1.2. Informed Consent

A copy of the study information leaflet will be provided, and the participant will be given the opportunity to discuss details with the medical team. The participant can take as long as they wish to consider taking part in the study. If the participant is happy to take part and is eligible, they will be asked to sign a consent form. A letter will be sent to the participants' GP to confirm study participation.

1.3. Questionnaires

Questionnaires relating to quality of life (i.e., physical and mental health) and physical capacity to undertake the study.

1.4. Activity Level Assessment

A wrist watch will be given to each participant to measure objective physical activity for a 3-day period. The participant doesn't need to do anything during this period.

2. Day of Stem Cell Collection (Both Groups: 45-minute time commitment)

All participants will be attending the Birmingham Centre for Cellular Therapy and Transplant for their scheduled stem cell collection. It is important to note that all planned medical care will remain identical and medical procedures will not be altered based on group allocation (notably myeloma cohort). In addition to the donor's standard medical care, the below procedures will take place:

2.1. General Health Assessment

The medical team will measure participants' height, weight, waist circumference, resting heart rate, blood pressure and pulse. These procedures will run in parallel with the appointment with the consultant.

2.2. Electrocardiogram (ECG)

This is a simple test that checks heart rhythm and electrical activity. Sensors are attached to the

skin to detect electrical signals produced by the heart when it beats.
2.3. Group Allocation
Random allocation to either the cycling or the control group.

3. Cycling Group - Stem Cell Collection (3-4 hour time commitment)
In the cycling group, participants will continue with the stem cell collection as normal. In addition, pedals will be provided in front of the chair, and they will be asked to pedal lightly for 4 minutes every 20 minutes. This typically lasts for approximately 3-4 hours; however, there will be 16 minutes of complete rest in between each interval. The settings on the bike can be altered at any time to ensure that the cycling is perceived as '12' on the validated 'rating of perceived exertion' scale, ranging from '6-20' - this is deemed to be 'light intensity'. Participants will be under constant supervision by the members of the research and medical team during this time.

During the procedure, the following measures will be taken:
- Perceived exertion/ability to cope with cycling will be measured using the chart above prior to starting and periodically during the trials.
- Heart rate will be measured by using a wristwatch.
- Blood pressure will be monitored via an automated stress-testing blood pressure monitor using a cuff placed around the upper arm.
- Pedal speed.
- Cycling Power Output.
- Questionnaires relating to the level of comfort and symptoms experienced during and after the procedure (pain, tiredness, nausea, anxiety, drowsiness, appetite, well-being and shortness of breath)
- Overall satisfaction and feedback on the session.
- Blood Sampling - before and after the procedure, a small peripheral blood sample (20mL) will be collected into EDTA-coated vacutainers.

4. Control Group (3-4 hour time commitment)
In the control group, participants will continue with their stem cell collection as normal. Participants will be asked to complete questionnaires relating to their level of comfort and symptoms experienced during and after the procedure, as well as overall satisfaction and feedback on the session.

During the procedure, the following measures will be taken:
- Heart rate will be measured by using a wristwatch.
- Blood pressure will be monitored via an automated stress-testing blood pressure monitor using a cuff placed around their upper arm.
- Questionnaires relating to the level of comfort and symptoms experienced during and after the procedure (pain, tiredness, nausea, anxiety, drowsiness, appetite, well-being and shortness of breath)
- Overall satisfaction and feedback on the session.
- Blood Sampling - before and after the procedure, a small peripheral blood sample (20mL) will be collected into EDTA-coated vacutainers.

After the Stem Cell Collection - Interviews (1 hour time commitment)
The interviews with donors will focus on:
- Perceived acceptability of intra-apheresis cycling (e.g., benefits and challenges).
- Physical and emotional experiences during the procedure.
- Perceived benefits or burdens of participation.
- Suggestions for improving the protocol or participant experience.

These interviews will be conducted via an online video service and led by the research associate or chief investigator.

Survey
If the participant is happy to take part, a series of online questions will be put forward and should take around 10-15 minutes to complete. No identifiable data will be collected, but some special category data, such as age and ethnic origin, will be obtained; this will not be linked to the respondent. Questions will focus on lifestyle, quality of life, perceptions regarding cycling during a stem collection and more general questions about attitudes towards regular exercise.

Timeline of Research
The broad timetable for the stages of the research includes preparation, convening meetings /conducting interviews, interpreting and analysing findings, and preparing the final report.

Intervention Type
Other

Primary outcome(s)
1. Rate of stem cell collection measured using flow cytometry to quantify CD34+ cells collected per minute at the end of stem cell collection

Key secondary outcome(s)
1. Final CD34+ dose measured using flow cytometry to quantify CD34+ cells per kg of body mass at the end of stem cell collection

2. Time to achieve the target dose measured using flow cytometry to quantify CD34+ cells per hour and day at the end of stem cell collection

3. Engraftment outcomes measured using flow cytometry to quantify neutrophil, lymphocyte and platelet recovery at a time point following stem cell transplant

4. Feasibility outcomes measured using study data recording recruitment, adherence and attrition rate at the end of stem cell collection

5. Acceptability outcomes measured using symptom questionnaires: for autologous donors, the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) and the EORTC myeloma-specific module (EORTC QLQ-MY20); and, for allogenic donors, the Short Form-12 (SF-12) quality of life questionnaire, and an interview, at a time point during and following the stem cell collection

6. Physiological outcomes, including the rating of perceived exertion, continuous heart rate monitoring, pedal cadence, and cycling interval average power output measured using the Borg scale, a wristwatch (beats per minute and % of age-predicted heart rate maximum), and pedals at during the stem cell collection

7. Immunological outcomes measured using flow cytomtery to quantify concentrations of immune cell subsets at pre and post stem cell collection

Completion date
30/06/2027

Eligibility

Key inclusion criteria

1. Inclusion Criteria for Patient Donors
The donor can be included if they have/ are:
1.1. A clinical diagnosis of Myeloma
1.2. A scheduled autologous stem cell collection
1.3. > 18 years old
1.4. The capacity to consent to taking part in the study
1.5. A consultant determined score of '0' or '1' on the ECOG Performance Status Scale
1.6. Consultant and donor agree that donor is capable of lightly pedalling for a maximum of 12 minutes per hour during the stem cell collection

2. Inclusion Criteria for Volunteer Donors
The donor can be included if they have/ are:
2.1. > 18 years old
2.2. A scheduled allogeneic stem cell collection
2.3. The capacity to consent to taking part in the study
2.4. Are able to lightly pedal for a maximum of 12 minutes per hour of their stem cell collection, and their consultant agrees

3. Inclusion Criteria for Survey
3.1. > 18 years old
3.2. Have the capacity to consent to taking part in the study
3.3. All people with a clinical diagnosis of myeloma will be included
3.4. All people who have previously undertaken a peripheral blood stem cell collection will be included (patients with myeloma and allogeneic (volunteer matched) donors)
3.5. All healthcare professionals who have previously worked with donors receiving a peripheral blood stem cell collections will be included
3.6. Family members of close friends of people who have previously undertaken a peripheral blood stem cell collections will be included

4. Eligibility Criteria for Interviews (Donors)
A CYCLE participant in the STEM-Ex study

5. Eligibility Criteria for Interviews (Healthcare Professionals)
5.1. Directly involved in stem cell collections
5.2. Involved in the STEM-Ex study

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

110 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Exclusion Criteria for Patient Donors
The donor will be excluded if they have/ are:
1.1. Uncontrolled blood pressure
1.2. Previously had a stem cell transplant
1.3. Joint problems that might limit ability to cycle e.g., bony deposits, osteoarthritis, collapsed spine, spine compression and/or an unstable spine
1.4. An abnormal electrocardiogram (ECG), which measures heart rhythm
1.5. Additional health conditions that might put them at risk during this study e.g. brain and/or lung conditions
1.6. Pregnant or planning a pregnancy

2. Exclusion Criteria for Volunteer Donors
The donor will be excluded if they have/ are:
2.1. Uncontrolled blood pressure
2.2. Joint problems that might limit your ability to cycle e.g., osteoarthritis
2.3. An abnormal ECG measurement
2.4. Additional health conditions that might put them at risk for this study e.g. heart complications, brain and/or lung conditions
2.5. Pregnant or planning a pregnancy

3. Eligibility Criteria for Survey
Not fulfilling one of the three inclusion criteria

4. Eligibility Criteria for Interviews (Donors and Healthcare Professionals)
Not fulfilling one of the inclusion criteria

Date of first enrolment
29/06/2026

Date of final enrolment
31/03/2027

Locations

Countries of recruitment
United Kingdom

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham

England
B15 2GW

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Academy of Medical Sciences

Alternative Name(s)
The Academy of Medical Sciences

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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