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Does exercise change how many immune cells are in the blood during different stages of myeloma?

Submission date
30/06/2021

Recruitment status
No longer recruiting

Registration date
08/07/2021

Overall study status
Completed

Last Edited
04/02/2025

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Myeloma accounts for 10% of all blood cancer diagnoses in the UK and can be broken down into different stages. Patients with early myeloma do not usually have many symptoms and do not require treatment. Patients with myeloma symptoms are treated with chemotherapy followed by a second period of very high-dose chemotherapy with stem cell transplant. After successful treatment, patients are said to be in “myeloma remission”. However, some myeloma cells survive treatment by hiding in areas of the body other than blood and this is called minimal residual disease. Minimal residual disease eventually builds up and myeloma commonly relapses.

Research has shown that regular physical activity, such as walking regularly in everyday life, can reduce the development of myeloma. There is also evidence that structured exercise training might improve the way cancer treatments work, thought to be driven by changes in the immune system after exercise. Exercise may move immune cells into the blood so that they can find and kill tumour cells. By moving immune cells into the blood where treatments work best, exercise might improve the way treatments work. For these reasons, exercise might benefit myeloma therapy at all stages of disease including, early myeloma (to reduce disease progression), myeloma (to enhance treatments), and myeloma remission (after treatment, to reduce the build-up of minimal residual disease). However, it currently remains unknown if exercise can move immune cells into the blood in people with myeloma.

This study will investigate if exercise can temporarily increase the number of immune cells in the blood and if exercise can improve the way treatment works against myeloma tumour cells that are grown in a laboratory in three different groups of people with myeloma: pre-treatment, during treatment and after treatment has finished. Participants will be recruited from an active database at the Royal United Hospital, Bath.

Who can participate:
All participants recruited will be aged 18 years or more. Patients who are diagnosed with early myeloma (smouldering multiple myeloma) and who have not received any treatments can participate in the study. Additionally, patients diagnosed with multiple myeloma who have

either, finished their first cycle of induction therapy or, who are in myeloma remission following a successful stem cell transplant can participate in the study.

What does the study involve?
All participants who take part will complete a 30-minute bout of cycling. Blood samples will be taken before, after, and 30 minutes after exercise so that we can assess changes in the number of immune cells in the blood and, assess the function of immune cells in the blood combined with treatment against myeloma tumour cells in laboratories at the University of Bath.

What are the possible benefits and risks of participating?
After the study, participants will be given a report of their test results so that they know more about their blood pressure, body composition (body mass index [BMI], fat and muscle), and physical activity and fitness in comparison to the general public. Participants will also be given £5 to contribute towards travel costs to the Royal United Hospital Bath and the University of Bath.

Blood sampling carries small risks including slight pain, bleeding, bruising, and infection. A trained phlebotomist will take the blood following best practice so that these risks are minimised.

Exercise will make participants feel sweaty and out of breath. There is also a chance that a participant could get injured and during exercise, there is a slightly higher than normal risk of experiencing a cardiac event (e.g. heart attack). However, participants will be screened for any complications that could happen during exercise to rule these out before beginning the study.

Where is the study run from?
The University of Bath (UK)

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

Who is funding the study?
This trial is funded by the University of Bath, the Royal United Hospital Bath, and by a Cancer Research UK grant (UK)

Who is the main contact?
Dr Harrison Colier-Bain, hdcb20@bath.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Harrison Collier-Bain

ORCID ID
https://orcid.org/0009-0001-3734-0792

Contact details

Department for Health
University of Bath
Claverton Down
Bath
United Kingdom
BA2 7AY
+44 (0)7595492883
hdcb20@bath.ac.uk

Type(s)
Scientific

Contact name
Dr John Campbell

Contact details
Department for Health
University of Bath
Claverton Down
Bath
United Kingdom
BA2 7AY
+44 (0)1225 385495
jc2656@bath.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
277825

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 277825

Study information

Scientific Title
Characterising the effects of exercise on immune cells in blood across the myeloma survivorship continuum

Study objectives
An acute bout of exercise increases the frequency of natural killer (NK) cells, T cells, monocytes and B cells in the blood of patients with multiple myeloma and improves the cytotoxicity of NK cells against a myeloma tumour cell line with and without the addition of anti-myeloma therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/12/2021, East of England – Cambridgeshire and Hertfordshire REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 207 104 8265; cambsandherts.rec@hra.nhs.uk), ref: 21/EE/0202

Study design
Pilot single-centre Phase I trial

Primary study design
Interventional

Study type(s)
Other

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

Interventions
This study will investigate if an acute, 30-minute bout of static cycling can temporarily increase the number of immune cells in the blood and if exercise can improve the way anti-cancer treatments work against myelom tumour cells that are grown in a laboratory in three different groups of people with myeloma: pre-treatment, during treatment, and after treatment has finished. Participants will be recruited from an active database at the Royal united Hospital, Bath. Participants who take part will complete a 30-minute bout of cycling at the Royal Unites Hospital or the University of Bath. Blood samples will be taken before, after and 30-minutes after exercise so that changes in the number of immune cells in the blood and the function of immune cells in the blood combined with treatment against myeloma tumour cells can be assessed in laboratories at the University of Bath.

Intervention Type
Behavioural

Primary outcome(s)
The frequency of NK cells, T cells and monocytes in the blood will be measured using flow cytometry before exercise, immediately after exercise, and 30-minutes after exercise.

Key secondary outcome(s))
1. The frequency of polyclonal and clonotypic B cells will be measured using flow cytometry before exercise, immediately after exercise, and 30-minutes after exercise.
2. The cytotoxicity of NK cells will be measured using ex vivo assay models before exercise, immediately after exercise, and 30-minutes after exercise.
3. The efficacy of anti-myeloma therapies against a myeloma tumour cell line will be measured using ex vivo assay models before exercise, immediately after exercise, and 30-minutes after exercise.

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. A diagnosis of smouldering multiple myeloma who have not received any treatment.
2. A diagnosis of multiple myeloma who have either: completed their first cycle of induction therapy, or are in remission following a successful haematopoietic stem cell transplant.
3. Aged 18 years or over.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
23

Key exclusion criteria
1. World Health Organisation (WHO)/Eastern Cooperative Oncology Group (ECOG) performance status >1.
2. Deemed unsafe to exercise according to the Physical Activity Readiness Questionnaire (PARQ).
3. Any comorbidity that is likely to progress or be exacerbated over the course of the trial period.
4. Cognitive impairment deemed a risk by the healthcare team or participation in the trials (e.g. diagnosis of neurodegenerative disease).
5. Unable to understand explanations and/or provide informed consent.
6. Any condition and/or behaviour that would pose undue personal risk or introduce bias into the trial.

Date of first enrolment
01/01/2022

Date of final enrolment
31/07/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Royal United Hospital
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
University of Bath
Claverton Down
Bath
United Kingdom
BA2 7AY

Sponsor information

Organisation
University of Bath

ROR
https://ror.org/002h8g185

Funder(s)

Funder type
University/education

Funder Name
University of Bath

Alternative Name(s)
UniofBath

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location

United Kingdom

Funder Name
Royal United Hospital, Bath

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. Datasets generated from this study will be archived in the University of Bath Research Data Archive following the completion of the study.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/09/2024	04/02/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet version 5	11/11/2025	11/11/2025	No	Yes
Protocol file		12/12/2022	07/09/2023	No	No