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The blood vessel protecting cell response to exercise in people with and without type 1 diabetes

Submission date
20/08/2019

Recruitment status
No longer recruiting

Registration date
23/08/2019

Overall study status
Completed

Last Edited
18/09/2024

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Exercise mobilises endothelial progenitor cells (EPCs), a cell that circulates within the blood and plays a role in the repair and formation of new blood vessels in healthy individuals. Higher numbers of these cells are associated with better blood vessel function and reduced heart disease and are released into the circulation during and after exercise. While it is known that individuals with type 1 diabetes, older individuals and individuals with lower fitness levels have a reduced number of circulating EPCs at rest, it is not known what the response to exercise is in individuals with type 1 diabetes and to what extent clinical factors such as age, fitness level and inflammation influences the number of EPCs. This study will explore how numbers of EPCs at rest and after exercise differ between T1D and healthy participants, and will explore clinical factors that predict the numbers.

Who can participate?
Patients aged 18-65 with type 1 diabetes and age, sex and fitness-matched healthy volunteers

What does the study involve?
Participants with type 1 diabetes undergo a urine test and a mixed meal tolerance test. Both type 1 diabetes and healthy control participants undergo a graded exercise test before a fixed bout of moderate-intensity walking exercise for 45 minutes, with blood samples taken before, immediately after and 1 hour after the exercise to measure the numbers of EPCs in their blood.

What are the possible benefits and risks of participating?
Participants will find out about their individual responses to exercise, receive feedback on fitness, and contribute to the care and management of those with type 1 diabetes. The risks of taking part include experiencing low blood sugar, injury and muscle soreness.

Where is the study run from?
The study is being run by Newcastle University and takes place in the clinical research facility in the Royal Victoria Infirmary (UK)

When is the study starting and how long is it expected to run for?
October 2016 to September 2019

Who is funding the study?
1. Diabetes Research and Wellness Foundation (UK)
2. Newcastle University (UK)

Who is the main contact?
1. Dr Daniel West
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
V3 14/07/16

Study information

Scientific Title
Endothelial progenitor cell (EPCs) response to exercise in individuals with and without type 1 diabetes

Study objectives
Individuals with type 1 diabetes will have reduced numbers of EPCs and progenitor cells. Type 1 diabetes participants with higher residual beta-cell function, shorter duration of diabetes, younger age and better control will have increased numbers of these cells.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 02/09/2016, North East Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Dr, Newcastle upon Tyne, NE2 4NQ; Tel: +44 (0)207 104 8026; Email: nrescommittee.northeast-tyneandwearsouth@nhs.net), ref: 16/NE/0192
2. Approved 04/06/2018, Faculty of Medical Science Ethics Committee (Research & Innovation office, Faculty of Medical Sciences, Newcastle University, Newcastle upon Tyne, NE2 4HH; Tel: +44 (0)191 208 5301; Email: fmsethics@ncl.ac.uk), ref: 1516/5648/2018

Study design
Acute observational trial

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Type 1 diabetes

Interventions

30 patients with Type 1 diabetes with a wide range of ages, duration of diabetes, fitness, glycaemic control and residual beta-cell function will be recruited. Healthy controls who are age, gender and fitness matched will also be recruited. Type 1 diabetes participants will be identified using urinary C-peptide to Creatinine Ratio testing, and those eligible will complete a mixed meal tolerance test to establish maximal stimulated serum C-peptide concentrations. Both type 1 diabetes and healthy control participants will complete a graded exercise test to determine VO2peak before completing a fixed bout of moderate-intensity walking exercise at 60% VO2 peak for 45 minutes, with blood samples taken before, immediately after and 1 hour after the exercise.

Intervention Type
Other

Primary outcome(s)
Number of EPCs (CD34+, CD45dim, VEGFR2 and CD34+, CD45dim, CD31+) measured by flow cytometry pre, immediately post and 1-hour post the exercise test between type 1 diabetes and healthy controls

Key secondary outcome(s))
1. Clinical factors at baseline:
1.1. Fitness measured using graded exercise VO2peak test
1.2. Glycaemic control measured by CGM time in range/in hypoglycaemia/hyperglycaemia and glycaemic variability parameters and HbA1c via commercially available assay test
1.3. Residual beta cell function measured by stimulated serum C-peptide MMTT via commercially available assay test
2. Number of progenitor cells ((1) CD34+ (2) CD34+, CD45dim (3) CD34+, CD45bright (4) CD34+, CD31+ (5) CD34+, VEGFR2+ (6) CD34+, CD45bright, CD31+ (7) CD34+, CD45bright, VEGFR2+) measured by flow cytometry pre, immediately post and 1-hour post the exercise test in participants with type 1 diabetes and healthy controls
3. Number of EPCs and progenitors expressing chemokine receptors (CXCR4, CXCR7) and the Mean Fluorescence Intensity (MFI) of these chemokine receptors measured using flow cytometry pre, immediately post and 1-hour post the exercise test in type 1 diabetes and healthy control participants

Completion date
30/09/2019

Eligibility

Key inclusion criteria
T1D:
1. Aged 18-65 years old
2. Diagnosed with T1D
3. Treated with exogenous insulin (pump or injection)
4. Free from diabetes complications

Healthy:
1. Aged 18-65 years old
2. Free from any chronic diseases

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
60

Key exclusion criteria
Cardiovascular disease or detection via ECG screening

Date of first enrolment
01/11/2016

Date of final enrolment
01/07/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Newcastle upon Tyne NHS Foundation Trust
Level 1 Regent Point Gosforth
Newcastle upon Tyne
United Kingdom
NE3 3HD

Sponsor information

Organisation
Newcastle University

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
University/education

Funder Name
Diabetes Research and Wellness Foundation

Alternative Name(s)
Diabetes Research & Wellness Foundation, Diabetes Research and Wellness Foundation UK, DRWF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Faculty of Medical Sciences, Newcastle University

Alternative Name(s)
FMS

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/07/2021	19/07/2021	Yes	No
Results article		11/02/2022	06/09/2023	Yes	No
Results article		25/04/2024	18/09/2024	Yes	No
HRA research summary			28/06/2023	No	No