ISRCTN50072340 https://doi.org/10.1186/ISRCTN50072340

Do the remaining insulin-producing cells in people with type 1 diabetes help to maintain good glucose control after exercise?

Submission date
15/05/2019

Recruitment status
No longer recruiting

Registration date
24/05/2019

Overall study status
Completed

Last Edited
14/06/2023

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
When people with Type 1 diabetes exercise, some experience hypoglycaemia (low blood sugar [glucose]), while others do not; in some HbA1c (a marker of diabetes control) gets worse while in others it improves. Exercise is known to increase glucose variability leading to more time with high and low levels. It is now known that many people with long-standing type 1 diabetes can produce small amounts of insulin from the remaining beta-cells in the pancreas. It is unknown if this is important for limiting blood glucose variability at rest and around exercise, and may explain some of the wide variation that is observed in response to exercise in people with Type 1 diabetes. This study aims to examine how residual beta-cell function impacts on glucose control when physically active / exercising in people with Type 1 diabetes.

Who can participate?
Anyone aged 18-65 years old with clinically diagnosed Type 1 diabetes, treated with exogenous insulin (pump or injection), free from diabetes complications can participate.

What does the study involve?
Participants will be required to complete a mixed meal tolerance test and a period of moderate intensity walking exercise for 45 minutes, with blood samples and interstitial glucose recorded before and after exercise

What are the possible benefits and risks of participating?
The benefits of taking part include understanding your own individual responses to exercise, receiving feedback on cardiovascular fitness, and contributing to the care and management of those with Type 1 diabetes. The risks of taking part include experiencing hypoglycaemia, musculoskeletal injury and muscle soreness.

Where is the study run from?
Newcastle upon Tyne NHS Foundation Trust, UK.

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

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

Who is the main contact?
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Contact information

Type(s)
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
C-peptide and exercise in T1D V3 14/07/16

Study information

Scientific Title
The role of residual beta-cell function on post-exercise glycaemic variability in individuals with type 1 diabetes

Study objectives
Type 1 diabetes patients with residual beta-cell function demonstrate improved post-exercise glucose control

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/09/2016 North East Tyne & Wear South Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Dr, Newcastle upon Tyne NE2 4NQ; 0207 104 8026; nrescommittee.northeast-tyneandwearsouth@nhs.net), ref: 16/NE/0192

Study design
Acute observational trial

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Type 1 diabetes

Interventions
Patients with Type 1 diabetes with a wide range of residual beta-cell function (from negative to clinically significant) will be recruited. Participants will be identified using urinary C-peptide Creatinine Ratio testing, and those eligible will complete a mixed meal tolerance test to establish maximal stimulated serum C-peptide concentrations. Participants will then complete a fixed bout of moderate intensity walking exercise at 60% VO2 peak for 45 minutes, with blood samples and interstitial glucose recorded before and after exercise.

Intervention Type
Behavioural

Primary outcome measure
The amount of time interstitial glucose is spent in euglycaemia measured using blinded interstitial continuous glucose monitoring

Secondary outcome measures
1. Glycaemic variability (SD, CV%, MAGE, J-Index, CONGA, MAG, M-value)
2. Time spent: hypoglycaemic (<3.9mmol/L, <3.0mmol/L), hyperglycaemic (>10mmol/L, >13.9mmol/L, >16.7mmol/L)
3. Hypoglycaemia stage 1 (<3.9mmol/L for 15+ minutes) and stage 2 (<3.0mmol/L for 15+ minutes) and hyperglycaemia incidence level 1 (>10mmol for 15+ minutes) and level 2 (>13.9mmol for 15+ minutes)
4. Corrective bolus/carbohydrate intake

Overall study start date
01/08/2015

Completion date
01/09/2019

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. Type 1 diabetes participants duration of disease less than 1 year
2. HbA1c > 10% (86 mmol/mol)
3. Unable to complete maximal exercise test

Date of first enrolment
01/10/2016

Date of final enrolment
31/05/2019

Locations

Countries of recruitment
England

United Kingdom

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

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The Medical School
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Sponsor type
University/education

Website
https://www.ncl.ac.uk/

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
Research organisation

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
Newcastle University

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/01/2020

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	results	01/10/2020	05/10/2020	Yes	No
Results article		10/03/2022	14/06/2023	Yes	No
HRA research summary			28/06/2023	No	No