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How does exercise impact bone turnover in people with and without Type 1 diabetes?

Submission date
15/04/2019

Recruitment status
No longer recruiting

Registration date
26/04/2019

Overall study status
Completed

Last Edited
03/09/2021

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
Diabetes is a condition that causes a person's blood sugar level to become too high. Insulin is the hormone made by beta-cells in the pancreas and controls the amount of glucose in the blood. There are two main types of diabetes: Type 1 where the pancreas does not produce any insulin and type 2 where the pancreas does not produce enough insulin or the person's cells do not react to insulin. High blood glucose levels can damage the small blood vessels of the body, and an often underappreciated region are the small vessels that supply the bone. Diabetes is associated with an increased risk of fracture and worsening of bone health, however, there is little information on those with long duration Type 1 diabetes. As exercise is recommended to people with Type 1 diabetes, and exercise can impact bone health, it is important to understand how exercise influences bone metabolism in those with Type 1 diabetes. This study aims to examine how exercise impacts on bone health markers in people with long duration Type 1 diabetes.

Who can participate?
Participants will be recruited from the North East region of England. Participants will be free from muscle / skeletal injury, have no contraindications to exercise, and aged between 18-65. Those with Type 1 diabetes will have an HbA1c <10%, and be treated with exogenous insulin only.

What does the study involve?
After a resting and exercising exercise stress test to quantify maximum heart rate and peak oxygen uptake, participants will attend the Newcastle NIHR Clinical Research Facility (Royal Victoria Infirmary; Leazes Wing) at ~8 am. Participants are required to fast for 12 hours before this. A cannula will be placed in the vein of the participants non-dominant arm and resting blood samples will be collected. The Type 1 diabetes participants' glucose concentrations will be managed according to current international guidelines.
After 1 hour, participants will conduct 45 minutes of steady state walking exercise at a moderate intensity. Blood samples will be drawn periodically before and after the exercise test. At 1 hour after exercise, the participants will be fed and allowed to return home. Blood samples will be processed for various markers of bone metabolism.

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 and musculoskeletal injury.

Where is the study run from?
Newcastle NIHR Clinical Research Facility (Royal Victoria Infirmary; Leazes Wing), UK

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

Who is funding the study?
The study is funded by the research fellowship from Newcastle University to the chief investigator, Dr Daniel West

Who is the main contact?
Dr Daniel West, daniel.west@newcastle.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Daniel West

ORCID ID
http://orcid.org/0000-0003-2246-4925

Contact details
Institute of Cellular Medicine
Room M4.077, William Leech Building
Newcastle University
Newcastle upon Tyne
NE2 4HH
Newcastle upon Tyne
United Kingdom
NE2 4HH
0191 2087076
daniel.west@newcastle.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
201939

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS ID: 201939

Study information

Scientific Title
The bone metabolic response to exercise in people with and without Type 1 diabetes: an observational study

Study objectives
Type 1 diabetes patients demonstrate altered bone metabolism responses in response to exercise

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 20/02/2016 Newcastle University Faculty of Medical Sciences Ethics Committee (Framlington Place, Newcastle upon Tyne, NE2 4HH; 0191 2086000; res.policy@ncl.ac.uk), ref: 1516/6548/2018
2. Approved 15/07/2016 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
Observational case-control study

Primary study design
Observational

Secondary study design
Case-control study

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 and a control group of age, fitness, BMI, gender balanced, non-diabetes controls will be recruited.
Participants will complete a fixed bout of moderate intensity walking exercise at 60% VO2 peak for 45 minutes, with blood samples collected before and after exercise and assessed for markers of bone metabolism.

Intervention Type
Behavioural

Primary outcome measure
Changes in CTX, procollagen type 1 N-Terminal propeptide, and parathyroid hormone from rest, to immediately after exercise. These will be measured by routine biochemical assay.

Secondary outcome measures
Changes in ionised calcium, phospohate, calcium, albumin from rest, to immediately after exercise. These will be measured by routine biochemical assay.

Overall study start date
01/06/2015

Completion date
01/10/2019

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 (15 type 1 diabetes, 15 control)

Total final enrolment

Key exclusion criteria
1. Type 1 diabetes participants duration of disease less than 1 year
2. Type 1 diabetes HbA1c >10%
3. Musculoskeletal injury

Date of first enrolment
01/10/2016

Date of final enrolment
01/07/2019

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

Sponsor details
Faculty of Medical Sciences
The Medical School
Framlington Place
Newcastle upon Tyne
England
United Kingdom
NE2 4HH
+44 (0)191 208 6000
kay.howes@ncl.ac.uk

Sponsor type

University/education

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

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
University/education

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
01/04/2020

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		04/11/2020	03/09/2021	Yes	No
HRA research summary			28/06/2023	No	No