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Exploring the risks and benefits of exercise in adults with type 1 diabetes

Submission date
08/05/2018

Recruitment status
No longer recruiting

Registration date
26/05/2018

Overall study status
Completed

Last Edited
02/04/2019

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Regular exercise improves fitness, strength and well-being and reduces the risk of heart disease. It is recommended that people with type 1 diabetes should do at least 150 minutes per week of moderate to vigorous exercise. People with type 1 diabetes who exercise, particularly those who are training for endurance events such as half-marathons or triathlons, can have problems managing their glucose around exercise. These problems include difficulty controlling blood glucose during and immediately following exercise and unexplained severe low blood glucose, particularly at night following exercise. Although there is guidance on how best to manage these problems, these guidelines are based on experiments in which people with type 1 diabetes have exercised in laboratories where conditions are closely controlled. Some patients feel that the current exercise guidance is not useful for “real world” exercise.
This study aims to closely monitor glucose levels and other substances related to diabetes in people who are training for and running a half-marathon. We hope this will allow us to adapt the current guidance to help people with type 1 diabetes manage their glucose when doing exercise in the “real world”, and thus help people with type 1 diabetes who are planning to undertake such events in the future.

Who can participate?
Any adult with Type 1 diabetes who has signed up to run the Swansea Half Marathon on 24th June 2018 can participate in this observational study.

What does the study involve?
All participants will be required to undertake a series of tests. These tests must be done at 2 time points – 8 weeks before and 1 week before the half marathon. The tests will be the same at both times and will include completing a questionnaire and training diary, completing some blood and urine tests at home, and wearing a glucose-recording device. In addition, there is the option to take a test of the immune system at both these timepoints, and this will require blood to be taken at the participant's GP surgery. Participation in this study has been kept simple, other than the GP blood tests, which is optional.

What are the possible benefits and risks of participating?
We do not expect any significant risks to your health by taking part in the study. Doing the finger

prick test, GP blood test, and placement of the continuous glucose probe might cause some slight pain and bruising. Participants will not directly benefit from this observational study but the information that is obtained will be used to support and advise other people with type 1 diabetes who participate in exercise.

Where is the study run from?
Taunton Hospital Clinical Research Department

When is the study starting and how long is it expected to run for?
The study will start 8 weeks before the Swansea half Marathon (end of April 2018), and finish 2 weeks after the half Marathon (early July 2018).

Who is funding the study?
Taunton and Somerset NHS Trust

Who is the main contact?
Catherine Thompson, Catherine.Thompson@tst.nhs.uk

Contact information

Type(s)
Public

Contact name
Dr Rob Andrews

Contact details
Taunton and Somerset NHS Foundation Trust
Department of Clinical Research
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Additional identifiers

Integrated Research Application System (IRAS)
243496

Protocol serial number
IRAS project 243496

Study information

Scientific Title
Exploring the risks and benefits of exercise in adults with type 1 diabetes: a ‘real world’ study of patients with type 1 diabetes undertaking the Swansea Half Marathon

Acronym
EXTOD101

Study objectives
Regular exercise in people with type 1 diabetes (T1D) can result in considerable improvements in health and reduction in cardiovascular events and death. However, a large percentage of people with T1D are not active. Fear of hypoglycaemia and lack of knowledge on how to manage their diabetes are major barriers to exercise in people with T1D. Although guidance exists on how best to manage T1D for exercise, this is based on evidence from experiments that have been undertaken in controlled laboratory conditions and, as a result, patients continue to describe dissatisfaction with the quality and accuracy of the current exercise guidance when used in the 'real world'.
Very little is known about the frequency of hypoglycaemia and percentage of time spent in low and high blood glucose levels of patients with T1D training for or completing in an endurance event. Similarly little is known about what techniques patients employ to manage their glucose levels when training for or completing an endurance event.

By recruiting people with T1D who are training for and then run the Swansea Half Marathon our primary aims are to:
1. Determine the frequency of hypoglycaemia and percentage of time spent in low and high blood glucose levels of patients with T1D and the effect of 6 weeks of training on these
2. Determine the effect of running a half marathon on the frequency of hypoglycaemia and percentage of time spent in low and high blood glucose levels on the day of the event and for 2 weeks after the event
3. Record the different strategies used by the different participants to manage their T1D during training for and whilst completing a half marathon

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland REC 4, 30/04/2018, 18/WS/0074

Study design
Observational study

Primary study design
Observational

Study type(s)
Other

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

Interventions
Following enrolment and informed consent, participants will be required to undertake a series of tests. These tests will be undertaken at two time points – 6-8 weeks before and 1 week before the half-marathon. The tests will be identical at both these timepoints and will include
1. Completing a questionnaire on medical history, drug history, activity and hypoglycaemia awareness
2. Doing a home blood test for HbA1c, Lipid A and C-peptide
3. Doing a home urine test for C-peptide

4. In addition, there is the option to undertake a test of the immune system that will require a blood test to be undertaken at the participant's GP.
Participants will also be asked to complete a training diary from the start of the study until 2 weeks after the half marathon. They will also be asked to wear a continuous glucose monitor and upload data from this daily from the start of the study until 2 weeks after the half-marathon.

Intervention Type
Not Specified

Primary outcome(s)
1. Frequency of hypoglycaemia and percentage of time spent in low and high blood glucose levels during the 6 weeks of training. This will be purely descriptive and will be calculated from the continuous glucose monitors.
2. Frequency of hypoglycaemia and percentage of time spent in low and high blood glucose levels on the day of the race and for the 2 weeks after. This will be purely descriptive, and again will be calculated from the continuous glucose monitors.
3. Change in frequency of hypoglycaemia and percentage of time spent in low and high blood glucose levels between week 1 and week 6 (effect of training). This will be calculated from the continuous glucose monitors. These will be compared using a paired T test or a non-parametric Wilcoxon test if the change scores are not normally distributed. In a previous study that we have done, the mean and SD of frequency of hypoglycaemia and percentage of time spent in low and high blood glucose levels were 18.2 + 2.8 hypoglycaemic episodes (hypos) per week, 6.8 + 1.9% of time in low blood glucose levels and 33.7 + 5.4% in high blood glucose levels. This means with a 100 and 50 people respectively we would have the power to detect a 0.78 or 1.2 difference in hypos per week, a 0.5% or 0.8% difference in time spent in low blood glucose level and 1.5% and 2.2% difference in time in high blood glucose levels.
4. Collation of different strategies used by the different participants to manage their T1D during training for and whilst completing a half marathon. This will be purely descriptive and we be grouped into changes in carbohydrate and protein intake, changes in insulin dosages and the combination of both. This will be collected from the questionnaires and patient diary.

Key secondary outcome(s))
1. Change in average glucose control and lipids between week 1 (first test) and week 6 (second test). Glucose will be measured by HbA1c and lipids by total cholesterol, HDL, LDL and triglycerides. These will be compared using a paired T test or a non-parametric Wilcoxon test if the change scores are not normally distributed. In a previous study that we have done the mean and SD of HbA1c, HDL, LDL and triglycerides was 75 + 25 mmol/mol, 1.38 + 0.46 mmol/l, 3.05 + 0.78 mmol/l and 1.37 + 1.87 mmol/l respectively. This means with 100 and 50 people respectively we would have the power to detect a 7 or 10 mmol/mol difference in HbA1c, a 0.13 or 0.18 mmol /l in HDL, 0.22 or 0.3 mmol/L in LDL and 0.5 or 0.75 mmol/L in triglycerides.
2. Change in urinary C-peptides between week 1 (first test) and week 6 (second test). These will be compared using a paired T test or a non parametric Wilcoxon test if the change scores are not normally distributed. In a previous study that we have done the mean and SD of urinary C-peptide is 2.11 + 0.76 nmol/mmol. This means with 100 and 50 people respectively we would have the power to detect a 0.21 or 0.30 nmol/mmol difference in urinary C-peptide.
3. Change in T cell types, number and function between week 1 (first test) and week 6 (second test). This will be measured by standard immunology techniques - flow cytometry and cell culture. These will be compared using a paired T test or a non-parametric Wilcoxon test if the change scores are not normally distributed. This has not been looked at before in people with Type 1 diabetes but we have seen changes with an acute bout of exercise in 20 people with Type 1 diabetes so are confident if 20 or more people provide us with blood that we will see a

difference.
4. Association of C-peptide with hypoglycaamic rates and time spent in normal glucose range. C-peptide will be measured in blood and hypoglycaemic rates and time spent in normal range will come from continuous glucose monitor measurements. We are also particularly interested in the impact of C-peptide and anticipate those with high C-peptide will have lower rates of hypoglycaemia and less glucose variability during training. We will define high C-peptide as urine C-peptide of >0.6 nmol/mmol and compare rates of hypoglycaemia between those with high and low C-peptide levels using rate ratios, and compare standard measures of glucose variability (% of time in low, normal and high ranges) between the two groups. We will then explore the effect of other potential confounders such as length, type and intensity of exercise.
5. The C-peptide measured from the finger prick and blood card test will be compared to the C-peptide measured in the urine to work out the sensitivity and specificity of these tests.

Completion date
01/05/2019

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Type 1 diabetes (as defined by treatment with insulin)
3. Plan to participate in Swansea Half Marathon and eligible for participation (https://race-nation.com/jcp-swansea-half-marathon-2018)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/05/2018

Date of final enrolment
24/06/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Taunton and Somerset NHS Foundation Trust
Department of Clinical Research
Musgrove Park Hospital
Taunton
United Kingdom
TA1 5DA

Study participating centre
Dr Parth Narendran
University of Birmingham
Institute of Biomedical Research
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
Taunton and Somerset NHS Foundation Trust

ROR
https://ror.org/02y5f7327

Funder(s)

Funder type
Not defined

Funder Name
Sanofi

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Participant information sheet	version v1.1	11/03/2018	02/04/2019	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes