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The changes in blood glucose during weights exercise in individuals with type 1 diabetes, with a view to improve exercise-associated fluctuations in blood glucose

Submission date
10/10/2013

Recruitment status
No longer recruiting

Registration date
18/10/2013

Overall study status
Completed

Last Edited
14/07/2015

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
Regular physical exercise can help support the health and well being of individuals with type 1 diabetes. Unfortunately, however, individuals with type 1 diabetes respond to exercise with large fluctuation in blood glucose leading to low and high blood glucose (hypo- and hyperglycaemia). Prolonged and uncontrolled incidences of hypo- and hyperglycaemia can seriously damage health, and therefore many type 1 diabetes individuals are discouraged to exercise. Although guidelines area available to reduce fluctuations in blood glucose during aerobic exercise, our lack of understanding of resistance exercise, or weight-bearing exercise, in type 1 diabetes means that there are no firm guidelines for the safe and effective prescription of resistance exercise in the type 1 diabetes population. This three-part study is aimed to develop an understanding of blood glucose changes during different types of resistance exercise in type 1 diabetes, with a view to develop strategies which help those with type 1 diabetes to better manage blood glucose. The objectives of the study are:
- To determine the effect of different resistance exercise sessions on blood glucose in type 1 diabetes individuals.
- To develop a glycaemia management strategy that improves the stability of blood glucose after a resistance exercise session.

Who can participate?
Male and female with type 1 diabetes aged between 18 and 60 years, regularly active (i.e. taking part in physical activities 3+ times per week), free from any diabetes complications other than mild background retinopathy (a complication of diabetes that damages the retina and can lead to blindness) and not taking any prescribed medication other than insulin and are treated with a stable insulin regimen.

What does the study involve?
The study was split into three parts. In part A, participants attended the clinical research facility on four separate occasions. On each occasion, participants completed one of three different

resistance exercise sessions (15, 30 and 45 min) followed by a resting recovery period (lasting 60 min), or a control session during which participants remained inactive. For part B, participants attended the clinical research facility on two separate occasions. On each occassion, participants completed a low or moderate intensity resistance exercise session. For part A and B, the order in which the participants received the different resistance exercises or the control session was randomized (like tossing a coin). For part C, participants attended the clinical research facility for the final part of the study. Participants were prescribed an insulin strategy (formed from data collected during the part A and B study) to adopt during a resistance exercise session. Blood glucose and metabolites were measured during each part of the study.

What are the possible benefits and risks of participating?
Participants learned correct techniques for resistance exercise. An individualized exercise program was written for each participant, which was based on data collected during the testing period. Participants obtained new information about how their body responds to a range of exercise sessions. In particular, participants were able to understand why their blood glucose changed during resistance exercise and were subsequently able to better manage their blood glucose during exercise outside of the research facility. This type of exercise caused some physical discomfort during and after the exercise due to muscle soreness, but these discomforts were typically normal and tolerable in the physically active population recruited. The blood tests caused some discomfort, with some participants experiencing minor bruising and feelings of light-headedness. Other than these manageable discomforts no other adverse effects were recognised with this routine procedure. Nevertheless, participants were cared for in a controlled laboratory environment within the clinical research facility, at Swansea University, to minimize the possibility for this to occur.

Where is the study run from?
The study was conducted at one site, in the Clinical Research Facility, Institute of Life Sciences (building 2), Swansea University, Singleton Park, SA2 8PP. Participants were recruited and screened through the combined use of the Abertawe Bro Morgannwg University Health Board, Singleton Hospital, Swansea and the National Health Service.

When is the study starting and how long is it expected to run for?
The study started in March 2012 and was completed by April 2013. The main phases of participant recruitment were during March 2012 to May 2012 and from December 2012 to February 2013.

Who is funding the study?
This research was funded by the ERDF Convergence Operational Program, Welsh Government and co-funded by Swansea University.

Who is the main contact?
Daniel Turner, PhD Researcher Sport and Exercise Physiology, 451953@swansea.ac.uk
Dr. Richard M. Bracken, Associate Professor in Exercise Physiology and Biochemistry, Swansea University

Contact information

Type(s)
Scientific

Contact name

Mr Daniel Turner

Contact details
ILS-1 3rd Floor
Swansea University
Singleton Park
Swansea
United Kingdom
SA2 8PP
-
451953@swansea.ac.uk

Additional identifiers

Study information

Scientific Title
The glycaemic, metabolic, glucoregulatory and hormonal responses to resistance exercise in type 1 diabetes, with a view to develop strategies that ameliorate exercise-induced glycaemic imbalances

Study objectives
1. Performance of resistance exercise will disturb blood glucose leading to hyper- and/or hypo-glycaemia.
2. Manipulations in the duration and intensity of a resistance exercise session will alter the magnitude of glycaemic disturbances.
3. Strategic alterations in insulin and carbohydrate will help improve blood glucose stability after exercise.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Dyfed Powys Research Ethics Committee, March 2012, ref. 12/WA/0049

Study design
Interventional repeated measures design and randomized study

Primary study design
Interventional

Study type(s)
Diagnostic

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

Interventions
The study was split into three parts.

A preliminary session was used to test for maximal strength and familiarize participants with the trial protocols and correct lifting techniques for exercise. Participants then completed the following trials, in order of part A to C.

Part A, participants attended the clinical research facility on four separate occasions. On each occasion, participants completed one of three different resistance exercise sessions (15, 30 and 45 min sessions) at 70% of maximal strength followed by a resting recovery period (lasting 60 min), or a control trial during which participants remained sedentary. Sessions were performed in a randomized and counterbalanced order. Venous bloods were collected at rest, 0, 5, 15, 30 and 60 min and 24 hours post-exercise.

Part B, participants attended the clinical research facility on two separate occasions. On each occasion, participants completed a low or moderate intensity resistance exercise session. Sessions were performed in a randomized and counterbalanced order. Venous bloods were collected at rest, 0, 5, 20, 35, 65, 95 and 125 min post-exercise.

Part C, participants attended the clinical research facility for one final trial. Participants were prescribed an insulin strategy (formed from data collected during the preceding trials) to adopt during a resistance exercise session (also designed from the previous trials). Venous bloods were collected at rest, 0, 5, 20, 35, 65, 95 and 125 min post-exercise.

Intervention Type
Behavioural

Primary outcome(s)
To determine a strategy that improves the stability of blood glucose in response to resistance exercise. To this end, blood glucose concentrations were measured following different volume and intensity resistance exercise sessions. From this data, a dose of exogenous insulin that best alleviated exercise-induced glycaemic disturbances was determined. Blood glucose was measured on a metabolic analyser (GEM Premier 3000; Instrumentation Laboratories, UK).

Key secondary outcome(s)
Blood and serum metabolites (pH and lactate, cortisol, glucagon, catecholamines, serum insulin, growth hormone, interleukin-6, non-esterified fatty acids and creatine kinase) responses before, during and after different resistance exercise sessions with and without an glucose management strategy

Blood pH, lactate, extra-cellular fluid base-excess and K+ were analysed on a metabolic analyser (GEM Premier 3000; Instrumentation Laboratories, UK). Remaining venous blood from each sample were centrifuged for plasma and stored at -80°C for later determination of insulin (Invitron, UK), creatine kinase (ILab 300 Plus, UK), β-hydroxybutyrate (D-3-hydroxybutyrate; Randox Laboratories Ltd, Co. Antrim, UK), catecholamines (ELISA; Eagle Biosciences Inc, Nashua, NH, USA), growth hormone, IL-6 and cortisol (ELISA; RnD Systems, Minneapolis, MN, USA).

Completion date
30/04/2013

Eligibility

Key inclusion criteria

1. Male and female, aged between 18 and 60 years
2. Regularly active (i.e. partake in physical activities 3+ times per week)
3. Free from any diabetes complications other than mild background retinopathy
4. Not taking any prescribed medication other than insulin
5. Are treated with a stable insulin regimen composed of a combination of slow -acting insulin (e. g. glargine) and rapid–acting insulin analogues for 3+ months before the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Race, gender, ethnic origin, nationality, religion or beliefs and sexual orientation were not used as exclusion factors for this investigation.
In an effort to improve homogeneity in data, volunteers were excluded if they were:
1. Aged less than 18 years or over 60 years
2. Physically inactive (i.e. partake in physical activities less than 3 times per week)
3. Suffered from any diabetes complications apart from background diabetic retinopathy
4. Taking any prescribed medication other than insulin
5. On a non–stable insulin regimen for less than 3 months

Date of first enrolment
01/03/2012

Date of final enrolment
01/02/2013

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Swansea University
Swansea

United Kingdom
SA2 8PP

Sponsor information

Organisation
Swansea University (UK)

ROR
https://ror.org/053fq8t95

Funder(s)

Funder type
Government

Funder Name
Welsh Government (UK) - ERDF Convergence Operational Program

Funder Name
Swansea University (UK)

Alternative Name(s)
, Prifysgol Abertawe

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2014		Yes	No
Abstract results		13/03/2013		No	No
Abstract results		16/08/2013		No	No
Other publications	Turner D, Ayles M, Gray BJ, Bain SC, Luzio S, Rees ED, West DJ, Campbell MD, Bastin L, Bracken RM. Syncope during resistance exercise in an individual with type 1 diabetes. Practical Diabetes International , 30 (7): 290-293.	01/09/2013		Yes	No