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Effect of insulin therapy and dietary adjustments on performance during simulated soccer tests in people with type 1 diabetes

Submission date
03/01/2017

Recruitment status
No longer recruiting

Registration date
05/01/2017

Overall study status
Completed

Last Edited
25/07/2017

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Diabetes mellitus is a life-long condition where a person is unable to control their blood sugar levels. There are two main types of diabetes, type 1 (around 10% of cases) and type 2. In type 1 diabetes (T1DM) the immune system attacks specialised cells in the pancreas called β-cells (which are responsible for producing the hormone insulin). This means that the sufferer is unable to produce enough insulin to effectively control their blood sugar levels and so regularly inject insulin in order to keep their blood sugar levels in a healthy range. T1DM sufferers have a high risk of developing complications from their diabetes, such as heart or blood vessel disease (cardiovascular complications), and so they are advised to maintain a healthy lifestyle with regular physical activity. People with T1DM often develop low blood glucose events when they perform exercise, with uncomfortable side effects such as nausea, palpitations, weakness and, in extreme situations, loss of consciousness. A 4-Step strategy has been developed to maintain blood sugar levels throughout exercise to help avoid these complications. This is effective in continuous exercise, such as running or cycling. However, is well known that the demands of intermittent (stop-start) physical activity are different from continuous exercise. The aim of this study therefore is to find out whether a 4-Step strategy of dietary and therapeutic adjustments leads to a better performance at soccer (an intermittent type of exercise), cognitive function (mental processing) and blood sugar control.

Who can participate?
Adults with T1DM who regularly play soccer.

What does the study involve?
Participants are randomly allocated to take part in two study conditions in a random order. In both conditions, participants complete a series of soccer-based training exercises in two sessions (on day 21 and 42 of the study). The first study condition involves the 4-Step strategy of dietary and insulin adjustments on the days when they are training. This involves eating a meal 60 minutes before they exercise with a 50% insulin dose, a meal 60 minutes after exercising with a 50% insulin dose, a bedtime snack without an insulin dose and a 20% reduction in their basal insulin dose (background level of insulin needed 24 hours a day). Those in the second group

follow usual recommendations according to exercise guidelines in diabetes with regards to their diet and insulin regime on the days when they are training. At the start of each condition and after three months, participants have their physical performance assessed. At the same times and immediately after and the day after each training session, participants also complete a range of assessments to measure their cognitive function.

What are the possible benefits and risks of participating?
Participants may benefit from better control of their disease and with the prevention of future cardiovascular complications. There are no notable risks involved for participants.

Where is the study run from?
Costa Rican Association of Diabetes, Endocrinology and Metabolism (Costa Rica)

When is the study starting and how long is it expected to run for?
September 2016 to July 2018

Who is funding the study?
Medtronic Foundation (USA)

Who is the main contact?
Dr Javier Calvo
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CRC-ANPEDEM-2017-001

Study information

Scientific Title
Effect of insulin therapy and dietary adjustments on performance during simulated soccer tests in people with type 1 diabetes: study protocol for a randomized, cross-over, double-blinded, controlled trial

Study objectives
Through a 4-Step strategy of dietary and therapeutic adjustments, a better performance will be observed by persons with Type 1 Diabetes on soccer and cognitive evaluations, as well as a more stable control of glycemic parameters before, during and after exercise execution, indexed by continuos glucose monitoring measurements.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomized cross-over double-blinded controlled interventional trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Participants are randomized to receive two interventions in a random order using block-stratified randomization, with random 2-4 sized blocks and stratified by gender. A statistician non-related to the protocol will generate the randomization list using a web-based method

(http://www.randomizer.org) that will randomize the order of the interventions assigned. The assessment sessions will occur on two separate days separated by three weeks from each other as wash out period because of the cross over design of the trial.

Real 4-Step Method: Participants consume a 60 min pre-exercise meal with 50% of insulin dose, 60 min post-exercise low GI meal with 50% of insulin dose, bedtime low GI snack before sleep omitting insulin dose, and 20% reduction in basal insulin dose.

Sham 4-Step Method: Participants follow ADA's usual recommendations of care before, during and after exercise. This involves a 60 min pre-exercise meal with 75% of insulin dose, 60 min post-exercise medium GI meal with no reduction in insulin dose, bedtime medium GI snack before sleep omitting insulin dose, and no reduction in basal insulin dose.

Participants in both groups attend 7 study visits in each trial condition. These involve: review of eligibility criteria (pre-screening visit), demographic data, clinical evaluation and BMI measurement and laboratory evaluation (visit 1, day 0), theoretical and practical explanation of training exercises (visit 2, day 14), training sessions with simulated soccer exercises and cognitive evaluations (visits 3 and 6, days 21 and 42), revision of self-monitoring of blood glucose (visits 4 and 7, days 24 and 45) and efficacy of blinding assessment (visits 5 and 7, days 35 and 45).

The assessment sessions will occur on two separate days (visits 3 and 6) and them will be separated by three weeks from each other, and consist of both cognitive and physical activity evaluations. Furthermore, participants will be seen the day following each assessment visit (visits 4 and 7) during which cognitive testing and self-monitoring of blood glucose will be repeated. In the last visit (visit 7) the efficacy of blinding will be assessed by asking participants in which interventional arm they think they were allocated, and how confident they are about their answer.

Intervention Type
Mixed

Primary outcome measure
Physical and technical performance in soccer training sessions will be evaluated using the Loughborough Intermittent Shuttle Test – Prescribed and Self-Paced (LIST-P), the Loughborough Soccer Passing Test (LSPT) and the Loughborough Soccer Shooting Test (LSST) at baseline and 3 weeks in each study condition

Secondary outcome measures
1. Selective attention and mental processing speed are measured using the Stroop Test at baseline and three weeks, and immediately after finishing the soccer exercises and the day after each workout visit in each study condition
2. Sustained attention and psychomotor speed are measured using the Digit Vigilance Test at baseline and three weeks, and immediately after finishing the soccer exercises and the day after each workout visit in each study condition
3. Visuo-spatial short-term memory are measured using the Corsi Block-Tapping Task at baseline and three weeks, and immediately after finishing the soccer exercises and the day after each workout visit in each study condition
4. Visual sustained attention and working memory processes are measured using the Rapid Visual Information Processing task at baseline and three weeks, and immediately after finishing the soccer exercises and the day after each workout visit in each study condition

Overall study start date
01/09/2016

Completion date
31/07/2018

Eligibility

Key inclusion criteria
1. Age 18 years and over
2. More than two years of established T1D diagnosis
3. Stable insulin regimen in the past 6 months indexed by a less than 20% of changes in total insulin daily dose
4. HbA1c less than 9.0%
5. Weekly physical activity of 90 min or more
6. Participation in recreational or competitive soccer-related activities, at least four times per month
7. Able to provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
16

Key exclusion criteria
1. Any treatment regimen different from continuous subcutaneous insulin infusion or multiple daily insulin injections
2. Any use of medications (other than insulin) known to affect glycemic control including oral or parenteral steroids (except for inhaled steroids), metformin, SGLT2 inhibitors, GLP.1 agonists, thiazolidinediones, sulfonylureas, DPP-4 inhibitors, or any other oral antidiabetic therapy
3. Detectable C-peptide in serum
4. Cognitive impairment comprising any substantial decrease in alertness, language reception, or attention that might interfere with understanding instructions for motor and cognitive testing, not including hypoglycemia unawareness
5. Chronic kidney disease (glomerular filtration rate less than 90 ml·min-1)
6. Chronic liver failure (Child-Pugh B or C)
7. Advanced diabetic retinopathy
8. Pregnancy
9. Color blindness

Date of first enrolment
01/08/2017

Date of final enrolment
01/03/2018

Locations

Countries of recruitment
Costa Rica

Study participating centre
Asociación Nacional Pro Estudio de la Diabetes, Endocrinología y Metabolismo (ANPEDEM)
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Sponsor information

Organisation
Asociación Nacional Pro Estudio de la Diabetes, Endocrinología y Metabolismo

Sponsor details
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Sponsor type
Other

Website
www.anpedem.com

Funder(s)

Funder type
Industry

Funder Name
Medtronic Foundation

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal as Diabetes Care 6 months after trial end.

Intention to publish date
31/01/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Javier Calvo (javier.calvo@ucr.ac.cr) and Gabriel Torrealba (GTORREALBAACOSTA@partners.org)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/07/2017		Yes	No