Blood glucose monitoring in para-cyclists

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Primary Objective: The primary aim of this research is exploring the glucose levels during exercise and during the night in para cycling athletes.Secondary Objective(s): the secondary aims are 1) analyzing the agreement between glucose...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON51851

Source
ToetsingOnline

Brief title
ParaCGM

Condition

- Other condition

Synonym
Blood glucose regulation, blood sugar handling

Health condition

Bloed glucose regulatie van Parawielrenners

Research involving
Human

Sponsors and support

Primary sponsor: HAN university of applied sciences
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Blood Glucose, Continuous blood glucose monitor, Handbiking, Para-cycling

Outcome measures

Primary outcome

The primary endpoint of the current study is the blood glucose levels of the

participants as measured with the CGM

Secondary outcome

The secondary endpoint of the current study is the blood glucose levels of the

participants as measured with finger prick blood sampling.

Study description

Background summary

Glucose is the most important fuel during high intensity exercise (1). High blood glucose levels increase carbohydrate delivery to the muscles, which improves performance (2). Blood glucose homeostasis is tightly regulated by the liver and at an intensity of 60%VO2max the uptake of glucose by the muscles and secretion of glucose by the liver is similar, therefore blood glucose levels remain stable (3). However, during high intensity exercise (above 80%VO2max), catecholamine levels rise, causing a higher glucose production compared to the muscle glucose utilization (4). Therefore, at high intensity exercise the blood glucose levels rise (4). After 60-90 minutes of high intensity exercise the liver and muscle glycogen can be depleted (5), which will lead to a drop in blood glucose levels and also a drop in performance. Furthermore, low blood glucose levels during the night can hamper recovery after intense exercise. For optimal recovery, high muscle glycogen synthesis is necessary, however, the rate-limiting enzyme glycogen synthase, is lower at lower insulin and blood glucose levels (6). Moreover, low blood glucose levels can even be linked to amenorrhea in women and relative energy deficiency in sports (7). Therefore, it is important for athletes to prevent a significant drop in blood glucose levels both during exercise, daily life and during the night. To prevent significant drops in blood glucose, first the blood glucose levels need to be known. The most common and inexpensive method for blood glucose measurement is the finger prick blood sampling (8). However, this technique only allows for a single measurement, which does not reflect glucose concentrations and perturbation

throughout the day and exercise. Furthermore, a finger prick can be hard to perform during exercise, especially during hand cycling. Moreover, finger pricks can be painful and are more invasive compared to the newest generation factory calibrated continuous glucose monitoring (CGM) devices. These monitors were initially developed for diabetes mellitus patients but have now been optimized for athletes. One of those new CGM devices is the Abbott glucose sport biosensor. This device measures the blood glucose levels every minute for two consecutive weeks. Although the accuracy of these devices to measure blood glucose concentrations throughout the day is high, evidence on the accuracy during exercise is equivocal. During exercise the blood glucose values can rise to more than double the normal living values, which could decrease the accuracy of the measurement. Therefore, it is not known if this is a reliable and valid method to use in daily living and exercise for these athletes. More insight in the occurrence of low blood glucose levels during and after intense exercise and the blood glucose levels during the night can help sport nutritionists to adapt the nutritional strategy around competition, training and before sleep of their athletes. This is certainly important for para cyclists, since they rely on carbohydrates as their main fuel during training and competition. Furthermore, most of their competition races have a duration longer than 60 minutes, in which the glycogen stores can get depleted. Therefore, the perfect nutritional strategy based on their blood glucose levels can help with both their performance as well as recovery. Within the para cycling athletes various disabilities exist, with most of them having some kind of disability on the lower body. One such disability is spinal cord injury. These athletes can have an additional challenge regarding glucose metabolism. Spinal cord injury athletes who have a lesion above or between T5 and T9 can have an impaired neurotic stimulation of the adrenal gland (9, 10). The catecholamines produced by the adrenal gland can inhibit the insulin secretion, enhance the glucagon secretion and activate the glycogenolysis in most tissues (11, 12). All of these actions can increase the blood glucose levels. Therefore, the glucose homeostasis of spinal cord injury athletes can be impaired and the blood glucose levels are less likely to rise during high intensity exercise. For these athletes the blood glucose monitoring can be even more important for optimal performance and recovery.

Study objective

Primary Objective: The primary aim of this research is exploring the glucose levels during exercise and during the night in para cycling athletes.

Secondary Objective(s): the secondary aims are 1) analyzing the agreement between glucose concentrations assessed by CGM devices and finger prick blood sampling during daily living in para cycling athletes. 2) Analyzing the agreement between glucose concentrations assessed by CGM devices and finger prick blood sampling during exercise in para cycling athletes. 3) Analyzing if there is a difference in the glucose metabolism between spinal cord injury hand

cyclists and para cyclists with other disabilities.

Study design

Observational study over 2-week period to assess 24-h blood glucose profiles, including exercise and sleep, in para cyclists. The participants are elite level para cyclists, who compete at an international level. All measurements are conducted within a fourteen-day period, including one day of standardized training at 60 and 85% of self-reported VO2max. In the two-week period the participants will continue their regular training program. The timing, duration and intensity of all exercise sessions (in trainingpeaks app), and the timing of all main meals during this period will be recorded (food logging in Supersapiens app). Within this two-week period, three days with more standardized tests will occur (day A, B and C). On day A the participants will exercise at three standardized intensities (60 and 85% of self-reported VO2max and a maximal 1 minutes sprint) and during this exercise five finger prick blood samples will be collected. Furthermore, the participants will be asked to keep a detailed food diary on these days. On day B the participants will continue their normal training but they will also keep a food diary and will take a seven point finger prick blood sampling during the day. Day C is the same as day B except for the finger pricks.

Study burden and risks

• The placement of the CGM can be slightly painful, because of the small needle used to penetrate the skin.
• The finger pricks can be uncomfortable to slightly painful.
• The food logging and food diary will cost some time for the participants. The exercise logging however, is already done by the participants and therefore, should not consume any extra time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

Dutch Paralympic cyclists, this includes cyclists, tandem risders and hand bikers. All athletes must be between 16 and 60 years of age.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:
- Athletes with an injury which causes a diminished training intensity.
- Athletes with diabetes mellitus
- Athletes who use any medication that interferes with their blood glucose levels, such as lisinopril, albuterol, acetaminophen, atenolol
- Women who are pregnant or lactating

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2023
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	13-12-2022
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL82746.096.22

Study results

Date completed:	07-04-2023

Actual enrolment:	16