Effect of exercise on HbA1c at the National Diabetes Challenge: a point-of-care testing method

Published: 05-08-2019
Last updated: 10-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON47942

Source
ToetsingOnline

Brief title
Effect of exercise on HbA1c at the National Diabetes Challenge

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Blood sugar, Diabetes Mellitus

Research involving
Human

Sponsors and support

Primary sponsor: star-shl diagnostisch centrum
Source(s) of monetary or material Support: star-shl

Intervention

Keyword: Diabetes, HbA1c, Physical exercise, Point-of-care testing

Outcome measures

Primary outcome

Change in HbA1c in mmol / mol. The intervention is considered effective with a decrease in HbA1c of 10% or more (5.39 mmol / mol).

Secondary outcome

% of patients who reach the target value (53 mmol / mol or * 58 mmol / mol, depending on age, duration of illness and medication)

*% of patients going from orange (75 mmol / mol) to green (53 mmol / mol)

*% of patients going from red (91 mmol / mol) to green (53 mmol / mol)

* Experiences of patients with the POCT of HbA1c

* Change in well-being

* Change in weight

Study description

Background summary

The risk of microvascular and macrovascular complications in people with diabetes increases as the HbA1c value in the blood increases. The HbA1c value provides information about the average tuning of blood sugar for diabetics over a longer period of time.
Previous studies have shown that exercise has a positive influence on HbA1c in people with diabetes. Never before has repeated research been conducted into the effects of an intensive period of (organised) walking on blood HbA1c levels in the Dutch population of diabetes patients.

Study objective

The primary aim of the study is to increase knowledge about the short and

medium term effect of an intensive period of (organised) exercise on the level of HbA1c in the blood of diabetics. This can help caregivers in giving lifestyle advice to people with diabetes. Secondary objective is insight into experiences with a scientifically proven, accurate and reliable, but hardly used point-of-care testing method for determining the HbA1c content with blood from a finger prick. The results from this study can be used by GPs when choosing whether to use the new measurement method in their practices.

Study design

Cohort study.
Measurements:
- POCT measurement of HbA1c during last day of the National Diabetes Challenge, after 3 months and after 6 months
- Baseline value of HbA1c retrieved retrospectively at central laboratory
- Patient questionnaires during last week of National Diabetes Challenge, after 3 months and after 6 months

Study burden and risks

For participants, a drop of blood is collected at three moments by means of a finger prick. This takes place once during the closing event of the National Diabetes Challenge and twice at a star-shl service point. The physical burden for patients of the finger prick is very limited and the risks are nil. There is a time burden for patients due to the two extra visits to the star-shl service point and the completion of three times a short questionnaire. The questions will not entail any psychological burden; no sensitive topics will be discussed.

Contacts

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star-shl diagnostisch centrum

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NL
Scientific
star-shl diagnostisch centrum

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NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adult patient (18 years or older).
Diagnosed with Type 1 or 2 Diabetes Mellitus.
Participant in the National Diabetes Challenge.
Registered with one of the GP practices in the star-shl diagnostic center regions (Rotterdam region, Etten-Leur region).

Exclusion criteria

No informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	11-09-2019
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	05-08-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL70687.091.19
Other	NL7818