Biological variation of hemoglobin A1c in adult volunteers without diabetes mellitus during a two year period

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To determine the natural variation of HbA1c in a group of older volunteers without DM during a period of 2 years.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON46479

Source
ToetsingOnline

Brief title
Biological variation of hemoglobin A1c

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, sugar-related disorder

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Klinisch chemisch laboratorium Isala ziekenhuis Zwolle

Intervention

Keyword: A1c, Biological variation, Hemoglobin

Outcome measures

Primary outcome

The biological variation of HbA1c in older volunteers without DM for a period

of 2 years.

Secondary outcome

Not applicable.

Study description

Background summary

Monitoring the treatment of diabetes mellitus type 2 (DM2) patients takes place by measuring the glycated haemoglobin (HbA1c) concentration. HbA1c reflects the average blood glucose level over a period of 1-3 months. A change in HbA1c is clinically relevant if it exceeds the normal variation in HbA1c over time (measured in healthy individuals), termed the biological variation. Studies have already assessed the biological variation occurring within a few months, however patients diagnosed with DM2 generally are monitored at least once a year when their diabetes is relatively stable. Hence, monitoring of DM2 patients would benefit if the biological variation of HbA1c over 1-2 years is known. This would allow for better assessment of observed changes in HbA1c levels in patienst with DM2.

Study objective

To determine the natural variation of HbA1c in a group of older volunteers without DM during a period of 2 years.

Study design

Observational study.
Through email and flyers with study information personnel of the Isala hospital will be recruited as volunteers. About 40 volunteers (20 males, 20 females) without diabetes mellitus (DM) are followed for a period of 2 years. Five times a year (1x in +/- 11 weeks) they undergo a venapuncture for 2 test tubes of 4

ml blood each. E. Lenters-Westra (research analist) summons the volunteers each time, executes the venapunctures and asks about any medical particularities. She and A. Vos monitor the progress of the study. The venapunctures are performed at the clinical chemical laboratorium of the Isala hospital. De test tubes will be frozen and analyzed after 2 years at the end of the study. Blood from the test tubes are tested on HbA1c and additional tests that can possibly influence the HbA1c: hemoglobin, mean corpuscular volume, hematocrit, creatinine, urea, alanine transaminase, aspartate transaminase and gamma-glutamyltransferase. Abnormal test results will be shared with the volunteer.

Study burden and risks

Five times a year (once in +/- 11 weeks) during 2 years a venapuncture is performed and 2 test tubes of 4 ml each are collected during each venapuncture. Volunteers are asked at each venapuncture if there were any medical particularities after their previous venapuncture. Risk of complications because of the venapuncture are small. The result, the long-term biological variation in volunteers without DM, surpasses the minimal risk of complication during venapuncture. The venapunctures are performed on the same location where the volunteer works. Mean duration of the visit will be about 5-10 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Male or female
45 - 70 years old
No diabetes mellitus
The previous year no major diseases such as cancer and/or large operations
No immune system modulating medication

Exclusion criteria

Younger than 45 years or older than 70 years
Diabetes mellitus
The previous year major diseases like cancer of large operations

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	08-11-2018
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL63930.075.18