Genetic loci for Skin Fluorescence in type 1 Diabetes Mellitus

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The primary objective is to identify additional genetic loci associated with skin fluorescence in patients with type 1 diabetes Mellitus. Secondary we want to assess if the identified loci are also associated to HbA1C, or if alternative loci are...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON42373

Source
ToetsingOnline

Brief title
Genetic loci for SF

Condition

- Other condition
- Diabetic complications

Synonym
single nucleotide polymorphism, snip

Health condition

identificeren van SNPs die geassocieerd zijn met huid fluorescentie

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: Onderzoek budget hoofd onderzoeker.

Intervention

Keyword: AGEs, GWAS, Skin Fluorescence, type 1 Diabetes Mellitus

Outcome measures

Primary outcome

The primary outcome variable for the Genomic-Wide Association Study (GWAS) will

be Skin Auto Fluorescence (SAF).

Secondary outcome

Association of SNPs with HbA1c

Study description

Background summary

As Eny et al showed, genetic variation contributes to variance in Skin Fluorescence (SF) 1. However, not all of the familial correlation is explained by the NAT2 locus. Therefore, in this study, we propose to identify additional loci associated with SF, which we believe may improve future prediction of diabetic complications based on SF screening, as well as improve the prediction of type 2 diabetes risk in the general population

Study objective

The primary objective is to identify additional genetic loci associated with skin fluorescence in patients with type 1 diabetes Mellitus. Secondary we want to assess if the identified loci are also associated to HbA1C, or if alternative loci are associated solely with HbA1c.

Study design

cross-sectional observational study

Study burden and risks

Patient burden will be limited, as the participation can be completed during regular out-patient follow-up. Subjects will be asked to complete a questionnaire to collect demographic data, a single blood test is required as well as non-invasive measurement of SF and other Anthropometric.
No direct benefit from anticipation is expected for the subjects. However, this study may increase current understanding and thereby aid future treatment options, both for the patient as for the (diabetic) population in general. As this involves an observational study, no risks are expected.

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

Signed informed consent
Type 1 DM
Age * 18 years

Exclusion criteria

Subjects who lack mental capacity to make their own decision / subjects who have a legal-guardian for ongoing medical decisions (including but not limited to mental retardation, schizophrenia, bi-polar disorder, degenerative cognitive decline). ;Participant in life-line study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	350
Type:	Anticipated

Ethics review

Not approved

Date:	06-04-2017
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

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	NL55763.094.15