AURORA project: AGE and UKPDS Rejoined to Optimize Risk Assessment in diabetes type 2

Published: 19-10-2006
Last updated: 20-05-2024

The aim of the study is to assess the possible additive value of the AGE reader measurement in a group of hospital-controlled (high-risk) persons with type 2 DM.

Ethical review	Approved WMO
Status	Pending
Health condition type	Diabetic complications
Study type	Observational non invasive

Summary

ID

NL-OMON30029

Source
ToetsingOnline

Brief title
AURORA project

Condition

- Diabetic complications
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
diabetes, diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: GlaxoSmithKline,sponsoring door GSK van investigator-initiated onderzoek;zie ook onder

Intervention

Keyword: AGE, cardiovascular risk assessment, diabetes

Outcome measures

Primary outcome

Exisiting complications macrovascular according to ICD guidelines

Existing microvascular complications, according to standard classifications

degree: retinopathy, nephropathy, (neuropathy)

Optionally: inventarisation development complications above during follow-up

Secondary outcome

ïnventarisatie satisfaction of diabetes specialist about AGE reader as

contribution to future decision making in type 2 DM

Study description

Background summary

Current cardiovascular risk prediction models are no more than moderately effective and precise. This also holds for the only model available for type 2 diabetes, the socalled UKPDS risk engine model. Nevertheless, such models are used for importnat, lifelong treatment decisions, guideline even advise to use them. There is a clear need for additional tools to make predictions more accurate.
The AGE reader is a noninvasive device to assess the skin level of advanced glycation endproducts which have an important pathogenetic role in the development of diabetic complications. The AGE reader has been shown to be a strong and independent predictor of CVD in well-controlles type diabetes patients with short diabetes duration (Zwolle study). It provides predictive information in addition to conventional risk factors and scores.
The aim of the study is to assess the possible additive value of the AGE reader measurement in assessing the relation with existing (and optionally future) macrovascular and microvascular complications in a group of hospital-controlled

(high-risk) persons with type 2 DM.

Study objective

The aim of the study is to assess the possible additive value of the AGE reader measurement in a group of hospital-controlled (high-risk) persons with type 2 DM.

Study design

observational study with optional follow-up period

Study burden and risks

no burden, no risk

Contacts

Public
Universitair Medisch Centrum Groningen

Postbus 30001
9700 RB Groningen
Nederland
Scientific
Universitair Medisch Centrum Groningen

Postbus 30001
9700 RB Groningen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

type 2 diabetes mellitus

Exclusion criteria

hypothyroidism, use of medication inducing secondary hypetension, icterus, moderate-severe anemia (Hb < 6 mol/l), diseases affecting survival at short term, alcohol- or drugabuse, (recent, < 30 days) particpation other study, no consent form

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	1200
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL13883.042.06