AVENIR project:: AGE in Vascular risk Estimation and Normalisation by Intensified Reduction in diabetes type 2.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28161

Source Nationaal Trial Register

Brief title AVENIR

Health condition

diabetes mellitus type 2

Sponsors and support

Primary sponsor: University Medical Center Groningen Source(s) of monetary or material Support: Sanofi-Aventis BV

Intervention

Outcome measures

Primary outcome

Differences in primary (one-year change in medication and in systolic blood pressure) will be compared between both arms.

Secondary outcome

1. Changes overall in HbA1c, LDL-cholesterol, skin autofluorescence (AGE reader), UKPDS risk score between baseline and one year;

2. Changes in UKPDS score and SAF from baseline to 1 year between the group in whom CV risk estimated with SAF and that estimated with the UKPDS risk engine is (higher or lower class) than that estimated with the UKPDS risk score, compared to the group in whom both rsisk estimated are concordant;

3. Differences between the concordant and discordant groups in target treatment values of blood pressure and lipids used by the treating physician. This will be assessed using a questionnaire.

Study description

Background summary

This is an implementation study with two arms in patients with type II diabetes without known CV disease, treated by hospital-based physicians in internal medicine. For the patients randomised to the first arm the physicians will be provided with both the result of the UKPDS RE, and with the result and interpretation of the skin autofluorescence measurement. In the second arm the physicians will only be provided with the UKPDS RE result. Possible changes in medical treatment, and the values of blood pressure (primary end points) and lipids and glycemic control (secondary end points) will be assessed after one year.

Study objective

The UKPDS study showed that good glycemic control in patients with type 2 diabetes mellitus (DMT2) results in a significant reduction in microvascular complications. A long-term followup extension of the study revealed that early intervention and good glycemic control early in the disease process, will result in a long-term reduction in cardiovascular (CV) complications. A recent study in The Netherlands showed in line with similar observations in Scotland and the US that the mortality risk of patients with DMT2 that were relatively well controlled (HbA1c =7%) and treated (\geq 30% on statins and RAS inhibitors) has become comparable to that of the general population (Lutgers 2009). These results show that a normal life expectancy is achievable in patients with DMT2 when adequately controlled and treated. Good CV risk estimation is essential to guide such treatment.

The UKPDS risk engine is specifically developed to assess the morbidity and mortality risk in patients with DMT2 (Stevens 2001). However, in general and hospital practice this risk engine is still relatively little used , partly because of the large (10) number of parameters that has to be measured and filled-in, and because of the known limitations of the risk engine as a predictor. This emphasizes the importance of additional or alternative risk factors that can be

used to monitor the CV risk and to adjust or intensify treatment.

Skin auto fluorescence (SAF) was recently introduced as an alternative tool for cardiovascular risk assessment in diabetic patients andt has been shown to provide incremental predictive information to the UKPDS risk engine (Meerwaldt 2007; Lutgers 2009). In more than 20% of patients with DMT2 the addition of SAF to the UKPDS risk score leads to reclassification of low or medium risk patients to high risk patients, or visa versa. Preliminary results of the AURORA study in the Netherlands confirm that SAF has a high correlation with the presence of CV complications. The non-invasive nature of the SAF measurement makes this a potential valuable and important contribution to the currently available risk engines, especially for those patients without concurrent CV complications. The question is, however, whether this scientific evidence also translates into changes in clinical practice: Does the treating physician really uses the additional predictive information provided by the SAF measurement, and does this change his/her treatment policy?

Study design

08-11: Start inclusion;

10-12: End inclusion;

After one year follow up, end of study in latest included in 11-13.

Intervention

The aim of this implementation study is to investigate if the use of skin auto-fluorescence, provided tot the treating physician, will change his treatment policy. This will be tested by randomising patients to either the arm in which the physician only receives the UKPDS RE result, or the arm in which the physician receives both the UKPDS RE, and the SAF measurement result.

Contacts

Public

University Medical Center Groningen

U3.129
A.J. Smit
Groningen
The Netherlands
+31 (0)50 3614854
Scientific
University Medical Center Groningen

U3.129
A.J. Smit

Groningen The Netherlands +31 (0)50 3614854

Eligibility criteria

Inclusion criteria

- 1. Type 2 diabetes mellitus, based on usual WHO (2005) or ADA (2010) criteria;
- 2. Age 25-65 years;
- 3. Stratification for presence of known preexisting CV complications or not.

Exclusion criteria

1. Other conditions which may affect the interpretation of the UKPDS risk engine or skin autofluorescence measurements;

- 2. Persons from South Asian descent (UKPDS RE not valid in this group);
- 3. Diffuse skin disease especially on volar side lower arm (SAF measurement not valid);
- 4. Diseases threatening survival in short term;
- 5. Alcohol- or drug abuse;
- 6. (Recent, < 30 days) participation in another study;
- 7. No signed informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

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Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-08-2011
Enrollment:	800
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	28-07-2011
Application type:	First submission

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
NTR-new	NL2865
NTR-old	NTR3008
Other	METC UMCG : 2010/237
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A