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

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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 follow-up extension of the study revealed that early intervention and...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28161

Bron
Nationaal Trial Register

Verkorte titel
AVENIR

Aandoening

diabetes mellitus type 2

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: Sanofi-Aventis BV

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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 phsicians 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.

Doel van het onderzoek

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 follow-up 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 (≥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?

Onderzoeksopzet

08-11: Start inclusion;

10-12: End inclusion;

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

Onderzoeksproduct en/of interventie

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 phsician receives both the UKPDS RE, and the SAF measurement result.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2011
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-07-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2865
NTR-old	NTR3008
Ander register	METC UMCG : 2010/237
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A