

# Onderzoeken van vroege diagnose van Diabetes Mellitus type 2 gebaseerd op Traditionele Chinese diagnostische wijze middels 'MERID' diagnostiek, biofotonen meting, hartslag variabiliteits meting en systeem biologische metingen

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Zie Engelse samenvatting Objectives: Primary objective • To determine consistency in classification of DM type 2 in three categories as defined by Traditional Chinese Medicine (TCM) in pre-diabetic subjects Secondary objectives • To find relationships...

<b>Ethische beoordeling</b>	Goedgekeurd WMO
<b>Status</b>	Werving gestopt
<b>Type aandoening</b>	Glucosemetabolismestoornissen (incl. diabetes mellitus)
<b>Onderzoekstype</b>	Observationeel onderzoek, zonder invasieve metingen

## Samenvatting

### ID

NL-OMON31184

### Bron

ToetsingOnline

### Verkorte titel

Vroege diagnose van DM2

### Aandoening

- Glucosemetabolismestoornissen (incl. diabetes mellitus)
- Diabetescomplicaties

### Synoniemen aandoening

Diabetes Mellitus type 2, Suikerziekte

### Betreft onderzoek met

Mensen

## Ondersteuning

**Primaire sponsor:** TNO

**Overige ondersteuning:** Ministerie van VWS

## Onderzoeksproduct en/of interventie

**Trefwoord:** Diabetes Mellitus type 2, Systems biologische metingen, TCM, Vroege diagnose

## Uitkomstmaten

### Primaire uitkomstmaten

Zie Engelse samenvatting

TCM Diagnosis:

Identification of DM type 2 based on TCM, diagnosed independently by 3 physicians and classified in Upper Xiao, Middle Xiao and Lower Xiao. Diagnosis will be considered consistent when 80% of the subjects are assigned to the same category by each physician. In case subjects are classified differently, then each subject will be evaluated by the three physicians together, and will then finally be reclassified.

Other measurements:

General measurements as BMI, waist circumference, blood pressure and heart rate variability will be conducted.

Next to these measurements also the following parameters will be established.

Biophoton emission: a recording based on analysis of intensity of both hands (ventral and dorsum) quantum stochastic nature, in combination with both right-left and dorsal-ventral symmetry of the energy field and balance of both hands.

Performance Meridian Measurements (MERID measurements): The \*MERID\* meridian method is based on the change of skin impedance after a given IR (infrared) stimulus to a Biological Active Point (BAP) which gives a reliable and reproducible measure for the energy status of that particular meridian and consequently of the related organ or organ system.

Heart rate variability:

Heart rate is affected by both sympathetic and parasympathetic input. These two branches of the autonomic control system affect both heart rate and changes in heart rate. Cardiac autonomic balance, also called sympatho-vagal balance, is the combined effect of parasympathetic (inhibitory) and sympathetic (excitatory) innervation of the heart and can be considered the main determinant of the regulation of heart rate and can be quantified by means of electrocardiography (ECG) measurements and spectral analysis. The sympathetic and parasympathetic activities have different effects on the frequency spectrum. High frequencies ( $>0.15$  Hz) are mostly affected by parasympathetic activity, whereas lower frequencies are affected by both sympathetic and parasympathetic activity. Heart rate frequency spectra are divided into three spectral bands: Low frequency: 0.02 - 0.06 Hz (related to temperature regulation);

Mid frequency: 0.07 - 0.14 Hz (related to resonance of vasomotor control); High frequency: 0.15 - 0.50 Hz (related to respiratory activity). During the study ECG will be recorded in every single subject for 30 minutes in semi-supine position. ECG's will be amplified, filtered and digitally recorded on a dedicated data acquisition system. The sampling frequency will be 512 Hz.

Metabolomics:

Metabolomics to be applied in this study consists of a number of methods based on LC-MS and GC-MS technology to determine (relative) concentrations of endogenous metabolites in biological samples (blood and urine). Based on the results of the TCM classification, a selection will be made for the samples (subjects) to be evaluated and the specific fields of interest for metabolomics will be further identified. Subsequently, the metabolomics methods available will be evaluated with respect to their suitability to this specific interests

### **Secundaire uitkomstmaten**

Zie Engelse samenvatting

None

## **Toelichting onderzoek**

### **Achtergrond van het onderzoek**

Zie Engelse samenvatting

Rationale: The global prevalence of diabetes, along with its devastating effects on life expectancy and quality of life, continues to increase. Worldwide, the total number of people with diabetes is projected to rise from about 171 million in 2000 to 336 million in the year 2030. Type 2 diabetes accounts for about 85 percent to 95 percent of all diagnosed cases of diabetes and is associated with a number of serious long-term complications, which are a major cause of morbidity, hospitalization and mortality in diabetic patients. More evidence is becoming available that both lifestyle and clinical intervention in the pre-diabetic condition are effective in slowing down progression of pre-diabetes to overt diabetes. Over many centuries, several forms of traditional medicine have developed which are often based on fundamental principles that differ from those of \*Western\* medicine. One of the most prominent characteristics of Traditional Chinese Medicine (TCM), is a more holistic approach to the functioning and

disfunctioning of living organisms. Important starting points are the five element (phase) theory and the principle that every healthy organism is in a Yin Yang balance and is considered to be a complex interplay between body and mind. Although, Western medicine relies on detailed classification of diseases, empirical investigations and treatments targeting those disorders, still it is showing an increased interest in traditional forms of medicine.

The progress in research, especially metabolomics, as the ultimate phenotyping, has been shown to enable the efficacy study of complex mixtures such as Traditional Chinese Medicine (TCM) in complex biological systems, bridging it with molecular pharmacology.

The present study is especially designed to explore biomarkers and tools for early diagnosis of diabetes mellitus type 2 with objective Western markers and TCM. The diagnostic views derived from classical TCM will be bridged with biochemical fingerprints (metabolomics) to enable the possibility to develop early diagnosis, specifically of DM type 2, an area which is not covered by Western approaches so far.

In the present study the non-invasive technologies that will be explored as system readout will be based on: meridian-measurements (infrared), biophoton emission and heart rate variability (HRV). Integration of Western and TCM knowledge could be a break-through in (early) diagnosis of DM type 2.

## **Doel van het onderzoek**

Zie Engelse samenvatting

Objectives:

Primary objective

- To determine consistency in classification of DM type 2 in three categories as defined by Traditional Chinese Medicine (TCM) in pre-diabetic subjects

Secondary objectives

- To find relationships between diagnosis according to TCM and risk profile according to Western approach (fasting glucose and HbA1c in plasma, age, BMI, waist circumference)

- To find relationships between classification of risk for DM type 2 according to TCM and objective parameters (Biophoton, Infrared, HRV, Systems biomarkers)

## **Onderzoeksopzet**

Zie Engelse samenvatting

Study design:

This study is designed as an explorative study

## **Inschatting van belasting en risico**

Zie Engelse samenvatting

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

This study is set up as a study with an explorative character. No administration of substances will take place. All subjects will be subjected to seven non-invasive measurements, filling in a number of questionnaires and subjected to two minimal physical examinations. Blood sampling, in the fasting state, will be done at two determined time points (pre-study and in study) and will not exceed 20mL. Furthermore, one (spot) urine sample will be collected in the study.

Based on the abovementioned non-invasive assessments and the fact that no administration of substances will take place, the discomfort for the subjects in the study is minimal and the risk for participating subjects is negligible.

## Contactpersonen

### Publiek

TNO

Postbus 360  
3700 AJ  
Nederland

### Wetenschappelijk

TNO

Postbus 360  
3700 AJ  
Nederland

## Locaties

### Landen waar het onderzoek wordt uitgevoerd

Netherlands

## Deelname eisen

## Leeftijd

Volwassenen (18-64 jaar)  
65 jaar en ouder

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Man: >30 en <70 jaar  
Bloed glucose levels: >6.1 en < 6.9 mmol/L  
BMI: >26 en < 35 kg/m<sup>2</sup>

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Medicijn gebruik (Westerse of Chinese)  
Roken,  
Alcohol consumptie: meer dan 28 glazen per week  
(Afval) dieet volgend  
Vegetarisch, veganist of macrobioot  
Acupuncturistische behandeling ondergaand

# Onderzoeksopzet

## Opzet

**Type:** Observationeel onderzoek, zonder invasieve metingen

Blinding: Open / niet geblindeerd

Controle: Geen controle groep

Doel: Diagnostiek

## Deelname

Nederland

Status: Werving gestopt

(Verwachte) startdatum: 04-06-2007

Aantal proefpersonen: 50

Type: Werkelijke startdatum

## Ethische beoordeling

Goedgekeurd WMO

Soort:

Eerste indiening

Toetsingscommissie:

METC Brabant (Tilburg)

## 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
CCMO	NL17038.028.07