Exploration of early diagnosis of Diabetes Mellitus type 2 based on Traditional Chinese Medicine by 'MERID' diagnostics, biophoton measurements, heart rate variability and systems biology

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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 subjectsSecondary objectives•To find relationships between diagnosis according...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON31184

Source
ToetsingOnline

Brief title
Early diagnosis of DM2

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Diabetic complications

Synonym
Diabetes, Diabetes Mellitus type 2

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: Ministerie van VWS

Intervention

Keyword: Diabetes Mellitus type 2, Early diagnose, Systems biology, TCM

Outcome measures

Primary outcome

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 heartbeat 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 recorder 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.

Secondary outcome

None

Study description

Background summary

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.

Study objective

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)

Study design

Study design:
This study is designed as an explorative study

Study burden and risks

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.

Contacts

Public
TNO

Postbus 360
3700 AJ
Nederland
Scientific
TNO

Postbus 360
3700 AJ
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Male: > 30 to < 70 years
bloodglucose levels >6.1 to <6.9 mmol/L
BMI:>26 to <35 kg/m2

Exclusion criteria

On medication (Western or Chinese)

Smoking,
Alcohol consumption > 28 glasses /week
Reported slimming, vegan, vegetarian, macrobiotic
Acupuncture treatment

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-06-2007
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL17038.028.07