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Evaluating the relationship between the radial pulse wave and the progression of kidney disease in type 2 diabetic patients

Submission date
08/01/2018

Recruitment status
No longer recruiting

Registration date
17/01/2018

Overall study status
Completed

Last Edited
13/02/2024

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Diabetes mellitus (when the body cannot control the sugar levels in the blood) is a strong risk factor for kidney disease and heart disease. These diseases can cause death in diabetic patients. Early predictors of these two diseases can lead to early diagnosis and medical treatment to prevent adverse renal disease and cardiovascular events. Thus, the first aim of this observational study is to find the potential risk markers for kidney disease. The additional purpose is to assess the risk of cardiovascular events and evaluate the relationship between kidney disease and cardiovascular events.

Who can participate?
Adults aged 30 and older with type 2 diabetes.

What does the study involve?
Participants are provided with information sheets and obtain written informed consent. Information on lifestyle questionnaires and medical history (including renal and cardiovascular events and procedures) are updated in each follow-up visit. Participants are then invited to a clinic room for radial pressure wave measurement and ankle-brachial index measurement.

What are the possible benefits and risks of participating?
Doctors take the ABI-index and radial pulse spectrum as risk variables based on the study and previous research. The patients may benefit from early detection of kidney disease or cardiovascular risk in the future. The radial pulse measuring device and ankle-brachial measuring device are both non-invasive.

Where is the study run from?
Taipei City Hospital (Taiwan)

When is the study starting and how long is it expected to run for?
December 2016 to February 2020

Who is funding the study?
Taipei City Hospital (Taiwan)

Who is the main contact?
1. Dr Kuo-Meng Liao (Public)
2. Dr Chi-Wei Chang (Scientific)

Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number
TCHIRB-10512113-E

Study information

Scientific Title

A study on progression diabetic nephropathy by harmonic analysis of pressure pulse waveform

Study objectives
Diabetic nephropathy will affect the renal vascular bed and reflect on the radial pulse spectrum. Therefore, harmonics of radial pulse could be an risk marker for the progress of diabetic nephropathy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Taipei City Hospital, 25/01/2017, ref: TCHIRB-10512113-E. Extension granted 29/01/2019, ref: TCHIRB-10704114-E.

Study design
This is an non-invasive and observational study that focus on radial pulse spectrum in type 2 diabetic patients with and without nephropathy within 2 years. Both cross-sectional and longitudinal method included.

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Risk factors in diabetes care

Interventions
All subjects underwent radial pressure wave measurement. Spectrum analysis of radial pressure wave was calculated and transformed into Fourier series coefficients Cn and Pn.

The enrolled group is investigated between February 2017 to December 2018. Both oral and written information about the study is given to the subjects. Informed consent is obtained from subjects after receiving approval from the institutional review board of Taipei City Hospital. The enrolled patients receive radial pulse wave measurement and ABI measurement twice a year and two-year follow-up until the end of the study or quit the project.

The study consists of two clinical tests:
1. The cross-sectional part measures the radial, ankle, and brachial blood pressure wave when a person first joined this study. The radial pulse spectrum and the ankle-brachial index is derived from these two measurements. These two measurements are both noninvasive. The interactions among the kidney disease, the cardiovascular events, and the risk factors (including the radial pulse spectrum and ankle-brachial index) are evaluated. The medical records of subjects including the blood test, urine examination, medication history, and lifestyle questionnaires to investigate the risk confounder such as age, gender, body mass index, blood pressure, low-density cholesterol, high-density cholesterol, and smoke history are analysed.
2. The longitudinal part: This part takes the risk evaluation of cross-sectional cohort study as the baseline. We continue to measure the radial pulse spectrum and ankle-brachial index and record the new onset of kidney disease and cardiovascular events at 2-year intervals.

In both parts of the cross-sectional and longitudinal part, it builds up the clinical risk variables for type 2 diabetic patients with kidney disease and cardiovascular events. Those clinical variables are safe enough to facilitate in routine clinical practice and also are cost-effective to repeat within months. Thus, periodic screening for those risk factors may help the doctors to evaluate the conditions of patients with type 2 diabetes.

Intervention Type
Other

Primary outcome(s)
1. Radial blood pressure wave is assessed using a miniature pressure transducer (TD01C, Taiwan) at time of enrollment
2. Ankle-brachial index is assessed using vascular screening system (VaSera VS-1500N, Japan) at time of enrollment
3. Albumin-to-creatinine ratio level is assessed using urine test at time of enrollment
4. Estimated glomerular filtration rate level is assessed using blood test at time of enrollment
5. Events of composite renal end point:
5.1. Doubling of the serum creatinine level is assessed using blood test
5.2. End-stage renal disease is assessed from the medical record
5.3. Death is assessed from the medical history

Key secondary outcome(s))
Cardiovascular events and its risk factors, from the medical record at time of enrollment.

Completion date
28/02/2022

Eligibility

Key inclusion criteria
1. Type 2 diabetic patients
2. Aged 30 to 95 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
1911

Key exclusion criteria

Severe diseases or acute symptoms are excluded if the pressure wave measurement could not be performed.

Date of first enrolment
08/02/2017

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Taiwan

Study participating centre
Taipei City Hospital
Division of Endocrinology & Metabolism of Zhongxiao Branch
Taiwan
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Sponsor information

Organisation
Taipei City Hospital

ROR
https://ror.org/02gzfb532

Funder(s)

Funder type
University/education

Funder Name
Taipei City Hospital

Results and Publications

Individual participant data (IPD) sharing plan

All the data such as medical history and the results of pulse wave measurement and ABI-index were recorded in the database system of the Division of Endocrinology & Metabolism of Zhongxiao Branch of Taipei City Hospital and will be governed by Dr. Liao within the study duration. Part of the clinical data is available through official request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/09/2018	13/02/2024	Yes	No
Results article		01/02/2019	13/02/2024	Yes	No
Abstract results	Association with cerebrovascular disease and dementia	05/12/2019	09/11/2022	No	No
Other publications	Association with macrovascular and microvascular events	01/10/2019	07/09/2020	Yes	No
Other publications	Association with silent coronary artery disease and adverse cardiac events	23/10/2018	09/11/2022	Yes	No
Other publications	Association with adverse cardiac events	01/06/2019	29/12/2022	Yes	No
Other publications	Association with diabetic retinopathy	01/10/2022	29/12/2022	Yes	No
Other publications	Association with major adverse cardiovascular and microvascular events	01/11/2019	29/12/2022	Yes	No
Other publications	Association with silent myocardial ischemia	11/09/2018	29/12/2022	Yes	No
Protocol file	in Chinese version 4.0	24/01/2019	29/12/2022	No	No