

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

<b>Submission date</b> 08/01/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 17/01/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/02/2024	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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

**Contact name**  
Dr Kuo-Meng Liao

**Contact details**  
Taipei City Hospital  
Division of Endocrinology & Metabolism of Zhongxiao Branch  
No.87, Tongde Road  
Nangang District  
Taipei City 115  
Taipei  
Taiwan  
11556

**Type(s)**  
Scientific

**Contact name**  
Dr Chi-Wei Chang

**Contact details**  
Graduate Institute of Biomedical Electronics and Bioinformatics  
National Taiwan University  
Room 410  
Barry Lam Hall  
No.1, Sec.4  
Roosevelt Road  
Taipei  
Taiwan  
10617

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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

## Secondary study design

Longitudinal study

## Study setting(s)

Hospital

## Study type(s)

Screening

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## 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  $C_n$  and  $P_n$ .

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 measure**

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

## **Secondary outcome measures**

Cardiovascular events and its risk factors, from the medical record at time of enrollment.

## **Overall study start date**

01/12/2016

## **Completion date**

28/02/2022

# **Eligibility**

## **Key inclusion criteria**

1. Type 2 diabetic patients
2. Aged 30 to 95 years

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

2500

**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

11556

**Sponsor information****Organisation**

Taipei City Hospital

## Sponsor details

Division of Endocrinology & Metabolism of Zhongxiao Branch  
No.87, Tongde Road  
Nangang District  
Taipei City 115  
Taipei  
Taiwan  
11556

## Sponsor type

Hospital/treatment centre

## ROR

<https://ror.org/02gzfb532>

# Funder(s)

## Funder type

University/education

## Funder Name

Taipei City Hospital

# Results and Publications

## Publication and dissemination plan

We plan to publish the cross-sectional results in a high-impact peer-reviewed journal at 31/02/2018 and to publish the whole longitudinal results from 31/12/2018 to 31/02/2019.

## Intention to publish date

28/02/2022

## 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?
<a href="#">Other publications</a>	Association with macrovascular and microvascular events	01/10/2019	07/09/2020	Yes	No

<a href="#">Abstract results</a>	Association with cerebrovascular disease and dementia	05/12/2019	09/11/2022	No	No
<a href="#">Other publications</a>	Association with silent coronary artery disease and adverse cardiac events	23/10/2018	09/11/2022	Yes	No
<a href="#">Other publications</a>	Association with adverse cardiac events	01/06/2019	29/12/2022	Yes	No
<a href="#">Other publications</a>	Association with diabetic retinopathy	01/10/2022	29/12/2022	Yes	No
<a href="#">Other publications</a>	Association with major adverse cardiovascular and microvascular events	01/11/2019	29/12/2022	Yes	No
<a href="#">Other publications</a>	Association with silent myocardial ischemia	11/09/2018	29/12/2022	Yes	No
<a href="#">Protocol file</a>	in Chinese version 4.0	24/01/2019	29/12/2022	No	No
<a href="#">Results article</a>		11/09/2018	13/02/2024	Yes	No
<a href="#">Results article</a>		01/02/2019	13/02/2024	Yes	No