

Evaluating the relationship between the radial pulse wave and gynecological disease

Submission date 19/05/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 25/05/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/06/2024	Condition category Urological and Genital Diseases	<input checked="" type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Harmonic analysis has been proven to be used to assess circulation status. In this study, we will observe the correlation between various common gynecological diseases and harmonic indicators through harmonic analysis. It is expected that harmonic indicators may become risk indicators for common gynecological diseases.

Who can participate?

Adults aged 20 and older with gynecological diseases.

What does the study involve?

Participants are provided with information sheets and obtain written informed consent. Information on lifestyle questionnaires and medical history are updated in each follow-up visit. Participants are then invited to a clinic room for radial pressure wave measurement.

What are the possible benefits and risks of participating?

Doctors take the radial pulse spectrum as risk variables based on the study and previous research. The patients may benefit from early detection of gynecological diseases in the future. The radial pulse measuring device is 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?

April 2018 to March 2022

Who is funding the study?

Taipei City Hospital (Taiwan)

Who is the main contact?

1. Dr Chih-Yu Chen (Public), tpech.anthony@m2k.com.tw
2. Dr Sheng-Hung Wang (Scientific), rax.wang@miiann.com

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

TCHIRB-10703121-E

Study information

Scientific Title

A study on gynecological disease classification by harmonic analysis of pressure pulse waveform

Study objectives

Harmonic analysis has been proven to be used to assess circulation status. In this study, we will observe the correlation between various common gynecological diseases and harmonic indicators through harmonic analysis. It is expected that harmonic indicators may become risk indicators for common gynecological diseases.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/04/2018, Institutional Review Board of Taipei City Hospital (8F., No. 10, Sec. 4, Ren'ai Rd., Da'an Dist., Taipei City 106, Taiwan (R.O.C.); +886 227093600; no email provided), ref: TCHIRB-10703121-E. Extension granted 08/04/2019.

Study design

Non-invasive observational study

Primary study design

Observational

Secondary study design

Longitudinal study

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Risk factors in gynecological diseases

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 from April 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 while referral 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 blood pressure wave when a person first joined this study. The radial pulse spectrum index is derived from the measurement. The measurement

is noninvasive. The interactions among the various common gynecological diseases and the risk factors (including the radial pulse spectrum index) are evaluated. The medical records of subjects including the blood test, urine examination, medication history, and lifestyle questionnaires to investigate the risk confounded 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 record the new-onset gynecological diseases at 4-year intervals.

In both parts of the cross-sectional and longitudinal part, it builds up the clinical risk variables for patients with gynecological diseases. 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 gynecological diseases.

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. Hormones (such as E2, LH, FSH and Prolactin) are assessed using blood test at time of enrollment
3. CA-125 and AFP are assessed using blood test at time of enrollment

Secondary outcome measures

Physician diagnosis from the medical record at time of enrollment.

Overall study start date

01/04/2018

Completion date

31/03/2022

Eligibility

Key inclusion criteria

1. Patients with gynecological diseases
2. Over 20 years old

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

1,500

Total final enrolment

825

Key exclusion criteria

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

Date of first enrolment

08/05/2018

Date of final enrolment

31/03/2022

Locations

Countries of recruitment

Taiwan

Study participating centre

Taipei City Hospital

Department of Obstetrics and Gynecology

Renai Branch

Taipei

Taiwan

106

Sponsor information

Organisation

Taipei City Hospital

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://english.tch.gov.taipei/>

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Taipei City Hospital

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/03/2023

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		16/10/2019	13/09/2022	No	No
Abstract results		16/10/2019	13/09/2022	No	No
Abstract results		16/10/2019	13/09/2022	No	No
Abstract results		11/11/2019	13/09/2022	No	No
Results article		01/09/2021	13/09/2022	Yes	No
Results article		29/10/2021	13/09/2022	Yes	No
Protocol file			14/09/2022	No	No
Dataset			24/06/2024	No	No