

# Evaluating the relationship between the radial pulse wave and gynecological disease

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<b>Registration date</b> 25/05/2020	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 24/06/2024	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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?

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

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

## **Study type(s)**

Screening

## **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(s)**

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

### **Key secondary outcome(s)**

Physician diagnosis from the medical record at time of enrollment.

### **Completion date**

31/03/2022

## **Eligibility**

### **Key inclusion criteria**

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

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **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

## ROR

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

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Taipei City Hospital

# Results and Publications

## 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?
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<a href="#">Results article</a>	01/09/2021	13/09/2022	Yes	No
<a href="#">Results article</a>	29/10/2021	13/09/2022	Yes	No
<a href="#">Abstract results</a>	16/10/2019	13/09/2022	No	No
<a href="#">Abstract results</a>	16/10/2019	13/09/2022	No	No
<a href="#">Abstract results</a>	16/10/2019	13/09/2022	No	No
<a href="#">Abstract results</a>	11/11/2019	13/09/2022	No	No
<a href="#">Dataset</a>		24/06/2024	No	No
<a href="#">Protocol file</a>		14/09/2022	No	No