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Evaluating the relationship between the radial pulse wave and gynecological disease

Submission date
19/05/2020

Recruitment status
No longer recruiting

Registration date
25/05/2020

Overall study status
Completed

Last Edited
24/06/2024

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[X] 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
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Public

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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 Cn and Pn.

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
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Sponsor information

Organisation
Taipei City Hospital

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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