

A diminished ovarian reserve prediction cohort study

Submission date 06/06/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/06/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 13/02/2025	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Ovarian aging has garnered substantial attention in recent years due to a large proportion of women choosing to delay childbearing, which often causes difficulty with conception and carrying a pregnancy to full term. As the ovary ages the local microenvironment changes in ways that reduce oocyte quality and increase the rate of follicular depletion, which eventually results in menopause. Menopause is associated with accelerated systemic aging, greater chronic disease burden and increased all-cause mortality risk. This is experienced as a sharp decline in fertility around 35 years of age, which corresponds to declines in oocyte quality. Recently, factors like genetic, behavioral, psychological, and immunity contributed to an increased incidence of diminished ovarian reserve (DOR), and the prevalence showed a younger trend. If the DOR can be detected and intervened earlier, the process of ovarian aging might be delayed and fertility preserved. This study aims to evaluate alterations in basal body temperature (BT) and heart rate (HR) (recorded by a wearable device, the Huawei Watch GT-3) during the menstrual cycle. In addition, machine-learning algorithms will integrate BT and HR data to predict the ovarian reserve among DOR women and non-DOR women.

Who can participate?

Women aged between 18-45 years old

What does the study involve?

The study is conducted by online questionnaire survey, and the personal information of the researchers will be kept confidential. The study involves the tracking of menstrual cycles and prediction of DOR via measurements of basal BT and HR, and machine-learning algorithms.

What are the possible benefits and risks of participating?

Through this study, subjects can know the physiological profile of their ovaries and their position in the population, which can help subjects better consider and arrange birth plans, understand and prepare for perimenopause management in advance, effectively arrange life and work, etc., and improve the quality of life. This study has no intervention on the participants and the study is of low risk.

Where is the study run from?

Obstetrics and Gynecology Hospital of Fudan University, Shanghai, China

When is the study starting and how long is it expected to run for?

February 2024 to March 2025

Who is funding the study?

Huawei Device (Shenzhen) Co., Ltd

Who is the main contact?

Dr Yalong Liu, liu_yl1997@foxmail.com

Contact information

Type(s)

Public, Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Prediction of diminished ovarian reserve via measurements of basal body temperature and heart rate as well as machine-learning algorithm—a prospective cohort study

Acronym

PreDOR

Study objectives

This study aims to evaluate alterations in basal body temperature (BT) and heart rate (HR) (recorded by a wearable device, the Huawei Watch GT-3) during the menstrual cycle. In addition, machine-learning algorithms were developed that integrated BT and HR data to predict the ovarian reserve among DOR (diminished ovarian reserve) women and non-DOR women.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 06/02/2024, Medical Ethics Committee of Obstetrics and Gynecology Hospital of Fudan University (419 Fangxie Road, Huangpu District, Shanghai, China, 200011, China; +86 21 5351 3815; yanting_wu@163.com), ref: Obstetrics and Gynecology Column Review 2024-12

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital, Internet/virtual, Medical and other records, University/medical school/dental school

Study type(s)

Prevention, Quality of life, Screening

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Tracking of menstrual cycles and prediction of diminished ovarian reserve via wearable devices

Interventions

The study is conducted by online questionnaire survey, and the personal information of the participants will be kept confidential. The study involves tracking menstrual cycles and prediction of diminished ovarian reserve via measurements of basal body temperature and heart rate (HR) as well as machine-learning algorithms.

The study is a prospective observational cohort study conducted at the Obstetrics and Gynecology Hospital of Fudan University in Shanghai, China. All patients will be enrolled in an outpatient setting. At enrollment, participants completed baseline questionnaires with items on age, weight, height, marital status, educational attainment, occupation, age at menarche, smoking status, alcohol consumption, and history of pregnancy and childbirth. The participants also received a wearable sensor (Huawei Watch GT-3; Huawei Device Co, Ltd, Shenzhen, China), and a smartphone (Huawei Mate 30; Huawei Device Co, Ltd, Shenzhen, China) to record essential physiological data. Participants with regular menstrual cycles (adhering to FIGO 2018) will be followed up through two menstrual cycles, and those with irregular menstrual cycles will be followed up for two months and will be encouraged to remain in the cohort until they have completed 2 qualified menstrual cycles or 2 months, defined as synced data for 80% of the cycle durations. Extra medical costs will be reimbursed, and some allowance will be gifted at the end of their follow-up.

During the follow-up period, women will be asked to wear the Huawei Watch GT-3 every night while sleeping and to sync this data with their smartphones every morning. For data collection, the duration of continuous sleep had to exceed 4-6 hours every night. The Huawei Watch GT-3 measures HR and heart rate variability (HRV) continuously during sleep. It can also measure body temperature and data related to sleep quantity and sleep quality. Participants will be instructed to report menstruation on the smartphone by answering "yes" or "no" to the two questions (i.e., "Did your period start/end today?") every day.

Intervention Type

Mixed

Primary outcome measure

Fertility measured using a serum anti-mullerian hormone (AMH) blood test at baseline, which is determined on the 2nd-4th day of menstruation for patients with a regular menstrual cycle, and on any day for those with irregular menstrual cycle

Secondary outcome measures

Fertility measured using a basal hormone blood test (FSH, LH, E2, P, PRL, T, DHEA) at baseline and > 4 weeks, which is determined on the 2nd-4th day of menstruation for patients with regular menstrual cycle, and on any day for those with irregular menstrual cycle

Overall study start date

01/02/2024

Completion date

31/03/2025

Eligibility

Key inclusion criteria

1. Aged 18-45 years old
2. AMH < 1.1 ng/mL
3. Menstruation within at least 6 months
3. Willing to participate in the follow-up and sign the informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Female

Target number of participants

120

Total final enrolment

127

Key exclusion criteria

1. Menopause, pregnancy, lactation
2. Exogenous hormones within 3 months, history of ovarian surgery, planned exogenous hormone therapy
3. Suffering from other states or diseases that can affect heart rate, respiration, body temperature and sleep parameters: diseases of the cardiovascular system (hypertension, heart disease, arrhythmia, wearing a pacemaker, etc.), respiratory diseases, abnormalities of the thyroid function (hyperthyroidism/hypothyroidism, positive antibodies are not excluded), taking psychotropic medications
4. Severe systemic disease or any unstable disease or medical condition that, according to

medical criteria, may jeopardize patient safety and his/her compliance with the requirements of the study

Date of first enrolment

01/03/2024

Date of final enrolment

31/12/2024

Locations

Countries of recruitment

China

Study participating centre

Obstetrics and Gynecology Hospital of Fudan University

419 Fangxie Road, Huangpu District

Shanghai

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200011

Sponsor information

Organisation

Obstetrics and Gynecology Hospital of Fudan University

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Sponsor type

Hospital/treatment centre

Website

<https://www.fckyy.org.cn/>

ROR

<https://ror.org/04rhdtb47>

Funder(s)

Funder type

Industry

Funder Name

Huawei Technologies

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

China

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

30/06/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from liu_yl1997@foxmail.com or yanting_wu@163.com. The individual participant data that underlie the results reported in the article will be shared, after deidentification (text, tables, figures, and appendices). Data will be available immediately following publication and ending 5 years following article publication. Consent from participants was required and obtained. All data from participants will be anonymized, with all names, addresses and other personally identifiable information removed, and will be kept strictly confidential. There are no further ethical or legal restrictions.

IPD sharing plan summary

Available on request