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A diminished ovarian reserve prediction cohort study

Submission date	Recruitment status	[_] Prospectively registered
06/06/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/06/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
13/02/2025	Urological and Genital Diseases	[_] 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

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Prevention, Quality of life, Screening

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

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
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Sponsor information

Organisation
Obstetrics and Gynecology Hospital of Fudan University

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

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