ISRCTN16822938 https://doi.org/10.1186/ISRCTN16822938

Study to investigate the temperature and dissolved oxygen levels in the uterine cavity of females with normal menstrual cycles

Submission date
17/06/2025

Recruitment status
Recruiting

Registration date
03/07/2025

Overall study status
Ongoing

Last Edited
02/12/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The study aims to collect data on the temperature and dissolved oxygen levels in women during the different phases of their menstrual cycles. The trial will provide data to support treatments for women's uterine health.

Who can participate?
Women with regular menstrual cycles, between the ages of 18-42 years

What does the study involve?
Participants would be enrolled into one group and will have the uterine monitoring device implanted for 7 days only.

What are the possible benefits and risks of participating?
Possible benefits:
Participants will be helping the development of a new device that will improve the understanding of uterine health. The trial will provide data to support future women’s health treatment and revolutionise uterine health so women can make empowered decisions.

Participants will be compensated for their time, inconvenience, and the procedure carried out. If they attend the screening appointment and are eligible to take part in the study, they will be compensated a total of £700 for their travel expenses, the insertion of the device and the following days up to its removal.

Possible risks:
The common risks of any intrauterine device are as listed.
Insertion of the device can cause injury to the womb; an example would be perforation, which is a hole in the womb (approx. 2 in every 1000).
Pain/ discomfort (approx. 12 -22 in every 100), mild bleeding on insertion/removal (15 in every 100), and infection (approx. 2 in every 1000).
Insertion under ultrasound guidance will allow the gynaecologist to see where he is placing the

device and avoid as far as possible any injury to the womb. The pain and discomfort in most cases will be short-lasting, and you will be able to take painkillers prior to the insertion. Rarely, the pain may continue after insertion. In these instances, there is the option for the device to be removed early. There is also the option of having local anaesthetic in the cervix (neck of the womb) during insertion if you wish. The risk of infection is small and would be treatable with antibiotics. Infection could also lead to pelvic inflammatory disease or fertility problems.

Where is the study run from?
Verso Biosense Limited, UK, with multiple participating sites around the UK.

When is the study starting and how long is it expected to run for?
January 2023 to December 2025

Who is funding the study?
Verso Biosense Ltd, UK

Who is the main contact?
Main contact: Chief Investigator- Prof Roy Homburg, royhomburg@gmail.com
Sponsor Contact: Mariea Parvaz, Clinical Trials Manager, m.parvaz@versobiosense.com

Contact information

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Public, Scientific

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Type(s)
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Additional identifiers

Integrated Research Application System (IRAS)
316600

Central Portfolio Management System (CPMS)
57213

Study information

Scientific Title
Study to investigate and monitor the intra-uterine temperature and intra-uterine dissolved oxygen levels across 7 days in females with normal menstrual cycles.

Acronym
VB002

Study objectives
A comprehensive investigation has been performed into the available data around biophysical sensing in the reproductive tract. It concluded that very little human data exists. There is a limited number of devices designed to monitor the reproductive tract environment, namely dissolved oxygen (DO), temperature, and none monitor the in vivo environment. These parameters are deemed crucial in embryo development, and it is hoped that these data will identify optimal conditions and lead to the development of treatment. Also the available methods are thought to give inaccurate and imprecise measurements. The data made available through this sensing technology in utero may help to provide new insights into how best to optimize the in vitro embryo environment and allow for more precise and personalized fertility treatment, and to increase the chances of IVF success.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/02/2023, West Midlands - Edgbaston Research Ethics Committee (3rd Floor Barlow House, Manchester, M1 3DZ, United Kingdom; +44 (0)207 104 8155; edgbaston.rec@hra.nhs.uk), ref: 23/WM/0012

Study design
Multicenter feasibility non-randomised trial

Primary study design
Interventional

Study type(s)
Safety, Other

Health condition(s) or problem(s) studied
Reproductive health

Interventions
All participants would be enrolled into one group and will have the device implanted for 7 days only between days 14-21 of their menstrual cycle. The device will monitor uterine temperature and dissolved oxygen through the study week. Participants will have a follow-up call on days 2, 4 and 6, followed by a removal visit on day 7.

Intervention Type
Device

Phase
Phase I

Drug/device/biological/vaccine name(s)
IRIS system intrauterine monitoring device

Primary outcome(s)
Intrauterine dissolved oxygen levels and intrauterine temperature measured using data collected from the IRIS device over 7 days in healthy volunteer females with normal menstrual cycles.

Key secondary outcome(s))
1. Device safety will be assessed using the following variables:
1.1. Number and occurrence of known clinical risks measured using clinical observation and reporting at study completion
1.2. Adverse events measured using participant reports and clinical records at study completion
1.3. Analgesic consumption measured using data collected in a patient diary across seven days post-procedure
2. Device user acceptance will be assessed using the following variables:
2.1. Tolerance of device use measured using a patient diary across seven days post-procedure
2.2. Frequency of study withdrawal and completion measured using participant tracking at study completion
2.3. User experience measured using a patient questionnaire at a 3-day follow-up

Completion date
30/09/2026

Eligibility

Key inclusion criteria
1. Women with regular menstrual cycles of approximate even duration e.g between 21-35 days
2. Women who are at least 18 years of age and less than or equal to 42 years of age
3. Clinically suitable for insertion of an intra-uterine device in an outpatient setting
4. No chronic illness e.g. diabetes, autoimmune disorders
5. Patient able to comprehend and sign the Informed Consent prior to enrolment in the study
6. BMI range 20 to 27
7. Able and willing to use barrier contraception (male condoms) or abstain from sexual intercourse during the menstrual cycle of the trial period

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
42 years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Pregnant, breastfeeding or planning a pregnancy during the course of the trial.
2. Pregnancies within the previous 3 months
3. Using hormonal contraception/therapies
4. History of miscarriage
5. Birth abnormalities or complications from previous pregnancies
6. Uterine anatomical abnormalities which, in the opinion of the investigator, may complicate the placement and removal of the device.
7. Concomitant medical treatment for or has any significant disease or disorder which, in the opinion of the investigator, may put the participants at risk.
8. Known allergies to local anaesthetics, silicone and barium sulphate (both are components of the device)
9. Undergoing investigation for abnormal uterine bleeding.
10. Current pelvic inflammatory disease, cervicitis, current genital infection, conditions associated with increased susceptibility to infections, cervical dysplasia, uterine or cervical malignancy.
11. Concurrent use of body-worn medical electronic devices.
12. No pre-existing or historical conditions which may impact the outcomes of this study (e.g abnormal cx smear)
13. Planned overseas travel for the duration of the study
14. Unable to comply with the study protocol
15. Require X-rays or other medical scans for the duration of the study

Date of first enrolment
12/09/2024

Date of final enrolment
15/09/2026

Locations

Countries of recruitment

United Kingdom

England

Scotland

Study participating centre
Liverpool University Hospitals
Axess Sexual Health: The Beat, 6 David Lewis Street
Liverpool
England
L1 4A

Study participating centre
Liverpool University Hospitals
The Arch, Axess Sexual Health-Knowsley
2 Ellison Grove, Huyton
Liverpool
England
L36 9GA

Study participating centre
Clarewell Clinics Birmingham
40 Hylton Street
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England
B18 6HN

Study participating centre
Clarewell Clinics London
9 Ivor Place
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Study participating centre
Blackpool Teaching Hospitals NHS Foundation Trust
Victoria Hospital
Whinney Heys Road

Blackpool
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FY3 8NR

Study participating centre
Princess Anne Hospital
Coxford Road
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SO16 5YA

Sponsor information

Organisation
Verso Biosense Limited

Funder(s)

Funder type
Industry

Funder Name
Verso Biosense Ltd

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes