

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 No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/07/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/06/2025	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Study website

<https://clinicaltrials.versobiosense.com/>

Contact information

Type(s)

Public, Scientific

Contact name

Miss Mariea Parvaz

Contact details

Verso Biosense Limited

115B Innovation Drive

Abingdon

United Kingdom

OX14 4RZ

+44 (0)7785465955

m.parvaz@versobiosense.com

Type(s)

Principal Investigator

Contact name

Prof Roy Homburg

Contact details

University College London Hospitals NHS Foundation Trust

Women's Health Division, 250 Euston Road

London

United Kingdom

NW1 2BU
+44 (0)7484608134
royhomburg@gmail.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

316600

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital, Other

Study type(s)

Other, Safety

Participant information sheet

See study outputs table

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

Pharmaceutical study type(s)

Not Applicable

Phase

Phase I

Drug/device/biological/vaccine name(s)

IRIS system intrauterine monitoring device

Primary outcome measure

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.

Secondary outcome measures

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

Overall study start date

01/01/2023

Completion date

31/12/2025

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

42 Years

Sex

Female

Target number of participants

30

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

30/06/2025

Locations

Countries of recruitment

England

Scotland

United Kingdom

Study participating centre

Liverpool University Hospitals

Axess Sexual Health: The Beat, 6 David Lewis Street

Liverpool

United Kingdom

L1 4A

Study participating centre

Liverpool University Hospitals

The Arch, Axess Sexual Health-Knowsley

2 Ellison Grove, Huyton

Liverpool

United Kingdom

L36 9GA

Study participating centre

Clarewell Clinics Birmingham

40 Hylton Street
Birmingham
United Kingdom
B18 6HN

Study participating centre**Clarewell Clinics London**

9 Ivor Place
London
United Kingdom
NW1 6BY

Study participating centre**Blackpool Teaching Hospitals NHS Foundation Trust**

Victoria Hospital
Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre**Princess Anne Hospital**

Coxford Road
Southampton
United Kingdom
SO16 5YA

Sponsor information

Organisation

Verso Biosense Limited

Sponsor details

115B Innovation Drive, Milton
Abingdon
England
United Kingdom
OX14 4RZ

Sponsor type

Industry

Website

<https://www.versobiosense.com/>

Funder(s)

Funder type

Industry

Funder Name

Verso Biosense Ltd

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

31/12/2026

Individual participant data (IPD) sharing plan

The data- sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date