# Study with the IRIS System to investigate intrauterine temperature and intra-uterine oxygen levels, and the impact of sildenafil

Submission date	Recruitment status	Prospectively registered
19/06/2025	Recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
03/07/2025	Ongoing	Results
Last Edited	Condition category	Individual participant data
20/06/2025	Urological and Genital Diseases	[X] Record updated in last year

## Plain English summary of protocol

Background and study aims

This study is looking at how temperature and oxygen levels inside the uterus change during different phases of the menstrual cycle in women who have not become pregnant after at least one round of IVF (in vitro fertilisation). The goal is to better understand uterine health and support the development of new treatments to improve fertility outcomes.

## Who can participate?

Women aged 18 to 42 years who have completed at least one IVF treatment but have not conceived can take part in the study.

## What does the study involve?

Participants will be placed into one of two groups, depending on when a small monitoring device is inserted into the uterus—either between days 7–14 or days 15–22 of their menstrual cycle. The device stays in place for 7 days to collect data. Starting on the fourth day after the device is inserted, participants will also use a vaginal suppository containing Sildenafil (100 mg) once a day.

What are the possible benefits and risks of participating?

Taking part in this study may help researchers learn more about uterine health and improve fertility treatments in the future. As with any medical study, there may be some risks or discomfort from the device or medication, which will be explained in detail before joining.

Where is the study run from? London Women's Clinic (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)

## Contact information

#### Type(s)

Public, Scientific

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Principal investigator

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## Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Integrated Research Application System (IRAS)

319521

## ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

CPMS 64535

## Study information

#### Scientific Title

Study to investigate intra-uterine temperature and intra-uterine oxygen levels, and the impact of sildenafil

#### Acronym

**VB003** 

#### **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 are 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 the 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. The study is aimed at collecting data during the luteal phase of a menstrual cycle on temperature and dissolved oxygen in women with a previous IVF failure and looking at any impact of sildenafil on D0 and temperature.

#### Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 23/11/2023, London - Fulham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8084; fulham.rec@hra.nhs.uk), ref: 23/LO/0283

#### Study design

Multicenter feasibility non randomized trial

## Primary study design

Interventional

## Study type(s)

Other, Safety

## Health condition(s) or problem(s) studied

Reproductive health

#### **Interventions**

All participants would be enrolled into one of two groups (Group 1: Days 7-14 of the menstrual cycle, Group 2: Days 15-22 of the menstrual cycle) and will have the device implanted for 7 days. From Day 4 post insertion of the device, participant will administer Sildenafil (100 mg vaginal suppository per day).

The device will monitor uterine temperature and dissolved oxygen through the study week. Participants will have a follow up call on Day 2, Day 4 and Day 6 followed by a removal visit on Day 7.

#### Intervention Type

**Device** 

#### **Phase**

Phase I

## Drug/device/biological/vaccine name(s)

**IRIS** Device

#### Primary outcome(s)

To investigate the performance of the device measuring temperature and dissolved oxygen in the uterus during the mid-luteal phase before and after treatment with vaginal sildenafil in women who have failed to conceive after at least one completed IVF treatment. Quantitative data from the IRIS device will be collected across the 7 day study period. A post removal user experience questionnaire (study day 10/3 days post removal) will be conducted to collect qualitative data.

#### Key secondary outcome(s))

- 1. To assess reliability of the device in monitoring dissolved oxygen and temperature parameters. This will be measured by observing the baseline dissolved oxygen level range and change from baseline and 48 hours post Sildenafil administration.
- 2. Safety reporting by incidence of Adverse Events measured by use of medical notes in the case report forms, at all visits (study days 0, 2, 4, 6 and 7).
- 3. Brief Pain Inventory score measured using the visual analogue score (VAS) and recorded by patient in the patient diary across the 7 day study period as well as looking at clinical notes in the case reports forms (on study days 2, 4, 6 and 7).
- 4. Tolerance of the device and how much wearing the device interfered with patient ability to carry out activities will be measured by the patient and recorded in the patient diary across the 7 day study period. Tolerance of the device will be reported in the post removal user experience questionnaire (study day 10/3 days post removal).
- 5. Consumption of analgesics recorded by patient in the patient diary across the 7 day study period.
- 6. Patient retention will be measured by calculating the frequency of patients withdrawing and completing the study.

## Completion date

31/12/2025

## **Eligibility**

## Key inclusion criteria

- 1. Women with unexplained infertility who have undergone at least one embryo transfer cycle after IVF without achieving a pregnancy.
- 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 heterosexual intercourse during the menstrual cycle of the trial period.
- 8. Occurrence of one previous miscarriage is accepted.

#### Participant type(s)

**Population** 

#### Healthy volunteers allowed

No

#### Age group

Adult

## Lower age limit

18 years

## Upper age limit

42 years

#### Sex

Female

#### Kev exclusion criteria

- 1. Pregnant, breastfeeding or planning a pregnancy during the course of the trial.
- 2. Currently taking an oral contraceptive or other hormone therapy
- 3. History of recurrent miscarriage.
- 4. Birth abnormalities or complications from previous pregnancies
- 5. Uterine anatomical abnormalities which, in the opinion of the investigator, may complicate placing and removal of the device.
- 6. Concomitant medical treatment for or has any significant disease or disorder which, in the opinion of the investigator, may put the participants at risk.
- 7. Known allergies to local anaesthetic, silicone and barium sulphate (both are components of the device)
- 8. Known allergy to or medical contraindication for sildenafil
- 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 on 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-ray's or other medical scans for the duration of the study

#### Date of first enrolment

01/01/2024

#### Date of final enrolment

31/12/2025

## Locations

#### Countries of recruitment

United Kingdom

England

Study participating centre London Women's Clinic 113 & 115 Harley Street London **United Kingdom** W1G 6AP

## 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

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

## **Study outputs**

Date created Date added Peer reviewed? Patient-facing? Output type **Details** Participant information sheet 11/11/2025 11/11/2025 No