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

Submission date
19/06/2025

Recruitment status
Recruiting

Registration date
03/07/2025

Overall study status
Ongoing

Last Edited
20/06/2025

Condition category
Urological and Genital Diseases

[_] 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
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)

Who is the main contact?
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Study website
https://clinicaltrials.versobiosense.com

Contact information

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Public, Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
319521

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital, Other

Study type(s)
Other, Safety

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
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

Pharmaceutical study type(s)
Not Applicable

Phase
Phase I

Drug/device/biological/vaccine name(s)
IRIS Device

Primary outcome measure
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.

Secondary outcome measures
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.

Overall study start date

01/01/2023

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

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. 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
England

United Kingdom

Study participating centre
London Women's Clinic
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Sponsor information

Organisation
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Sponsor type
Industry

Website
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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