ISRCTN10654279 https://doi.org/10.1186/ISRCTN10654279

Real time monitoring of the womb environment using a novel device

Submission date	Recruitment status	[X] Prospectively registered
29/03/2021	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
31/03/2021	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
24/08/2021	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Doctors and researchers at the University of Southampton have developed a novel monitoring device that may in the future be offered to women who have problems becoming pregnant or who have recurrent miscarriages.

A small sensor device developed by Verso Biosense in collaboration with the University has the potential to monitor the environment inside the womb to detect changes in oxygen levels, acidity, and temperature, which are features considered to have an impact on embryo development. The purpose of this study is to determine how acceptable the insertion of this device is to women and whether the collection of information is successful.

Who can participate?
Women aged between 18 and 42 years recruited from subfertility/gynaecology outpatients clinic with or without reproductive disorders and no known chronic illnesses

What does the study involve?
The study involves having a device placed within the womb in an outpatient clinic in a sterile environment for up to 7 days. The device is designed to look like an intrauterine contraceptive device, for trained health care professionals to place into the uterus. It has an accompanying garment which the patient can wear as pants, and a detachable rechargeable reader, which together provides the means of powering the device, communicating signals, and retaining data. A member of the research team will provide comprehensive instructions around the use of the device and how the study will be conducted. Regular follow-up phone calls and user experience interviews will be part of the study.

What are the possible benefits and risks of participating?
It is not known how the device will impact humans, but previous animal studies have shown localised inflammatory reactions in the lining of the womb. However, it should be noted that the device shape and dimension has been designed specifically for the human and not animals. It is anticipated that the risks in taking part in this study to be comparable to that of a contraceptive device inserted inside the womb, as it carries the same shape, dimension, and features.

The common risks of the device are pain, discomfort and mild bleeding on insertion/removal, and infection. The pain and discomfort in most cases will be short-lasting and the participants 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 will be treatable with antibiotics.

Less common risks include injury to the womb or expulsion of the device. The device will be inserted under ultrasound guidance, so the risk of injury to the womb will be rare. If the device does fall out, participants are advised not to worry and to contact the research team, who will be able to support them with what they should do next. Very rarely, the device removal cords retract into the womb and their doctor may be required to use specialised equipment in an outpatient setting including a camera to assist with its removal. During the study period and whilst the device is inside the womb, they will need to use barrier contraception or abstain from sexual intercourse, as it is important that they do not get pregnant whilst the device is in.

The participants will be reimbursed for travel and parking costs related to attending this research study. But they will not directly get any personal benefit from taking part in this trial. However, they will be helping the development of a new test which in the future may be offered to women having problems conceiving or who have recurrent miscarriages.

Where is the study run from?
University of Southampton (UK) and Princess Anne Hospital (UK)

When is the study starting and how long is it expected to run for?
December 2019 to May 2022

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Prof Ying Cheong, Y.Cheong@soton.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Ying Cheong

ORCID ID
https://orcid.org/0000-0001-7687-4597

Contact details
University of Southampton
Coxford Road
Southampton
United Kingdom

SO16 5YA
+44 (0)2381206033
Y.Cheong@soton.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
263353

Central Portfolio Management System (CPMS)
44566

Study information

Scientific Title
Intra-Uterine SENSing using a batteryless, wireless intrauterine platform (U-SENSE)

Acronym
USENSE

Study objectives
To demonstrate the feasibility of a clinical trial, and the safe and effective use of the IRIS System with its target demographic across women with a spectrum of uterine receptivity

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/02/2020, HRA and HCRW (Health and Care Research Wales) (Health Research Authority, 2 Redman Place, Stratford, London, E20 1JQ; no telephone number available; approvals@hra.nhs.uk), ref: 20/SC/0056

Primary study design
Interventional

Study design
Non-randomized feasibility study

Study type(s)
Screening

Health condition(s) or problem(s) studied
Monitoring intrauterine parameters linked to fertilization

Interventions
The study will use the IRIS System to investigate the feasibility to recruit to a study to investigate the biophysical profile of dissolved oxygen (DO), pH, and temperature within the uterus of women with subfertility and amongst controls. Patients scheduled for the insertion of

IRIS IUMD in the outpatient clinic at Princess Anne Hospital at the Southampton University Hospitals NHS Foundation Trust and who meet the Inclusion/Exclusion criteria will be eligible for recruitment into the study.

The Investigators will be required to complete Case Report Forms (CRFs) in which information about the participants, the data described below, and any Adverse Events will be recorded. The study will include 25 women attending the fertility/gynaecological outpatient clinics, with or without diagnosed reproductive disorders. Participants will be advised to take barrier contraception or abstained from intercourse in the menstrual cycle of the trial period.

The device will be inserted as an outpatient procedure, with the position checked on ultrasound scan. Use of local anaesthetics can be applied by clinician digression and/or on patient request.

Prior to insertion of the device, the uterine (womb) dimensions will be measured using a vaginal ultrasound scan. At insertion, a speculum will be inserted in a sterile manner, and cervix (neck of the womb). The device will be inserted with the aid of an introducer similar to the insertion of an intrauterine coil. The details of the insertion will be noted on the CRF. Once the device is inserted, the patient is observed for up to 30 minutes, and then discharged once the device is confirmed technically functioning and the patient has tolerated the procedure well.

Patients will be given information and advice on possible side effects such as bleeding and pain, and an emergency phone contact before discharge.

The clinician researcher will provide a phone call follow up every 2 days until the day of removal (up to 7 days) and enquire about a standard set of clinical questions set out in the CRF. In the event of any adverse events that requires device removal, or the participant chooses to discontinue the study, immediate arrangement will be made to remove the device in clinic or an appropriate clinical environment according to need. At removal of the device, an endometrial fluid and biopsy sample will be taken using the fine catheter (usually used for embryo transfer) and a sampler used for removing small amount of lining of the womb (again a procedure commonly perform in outpatients to examine the womb lining) respectively. The samples will be stored appropriately and later send for histological examination to check for inflammation.

Once the device is removed, the researcher will arrange a follow up phone call 3 days after the removal.

Any side effects or adverse events reported in the process of the study will be dealt with according to standard clinical care.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
1. Clinical feasibility measured using the following:
1.1. Rate of recruitment and retention of participants from Investigator's notes between baseline and 10 days
1.2. Ease of device insertion measured at baseline, carriage for up to 7 days measured between baseline and 7 days, and ease of removal measured at 7 days
1.3. Use of the device in women with a spectrum of endometrial receptivity recorded at nurse

telephone follow-up at 1, 3, 5, 7, and 10 days
2. Safety measured using the incidence of any device-related AEs that are within the acceptable limits defined by Vivoplex's Risk Management File recorded at nurse telephone follow-up at 1, 3, 5, 7, and 10 days
3. Technical feasibility measured as the rate of successful temperature, pH, and dissolved oxygen data capture based on the schedule of data transmission of the device between baseline and 7 days

Key secondary outcome(s)
1. Clinical safety measured from the presence or report of the following clinical side effects /adverse events between baseline and 10 days:
1.1. Evidence of clinically confirmed or suspected uterine/pelvic infection
1.2. Pelvic pain at or after insertion
1.3. Irregular vaginal bleeding
1.4. Device expulsion or perforation
2. Device usability measured from device-related AEs associated with use-error between baseline and 10 days
3. Technical safety measured using body temperature between baseline and 7 days

Completion date
30/05/2022

Eligibility

Key inclusion criteria
1. Women recruited from the subfertility/gynaecology outpatients clinic with or without reproductive disorders
2. Aged between 18 and 42 years inclusive
3. Clinically suitable for insertion of device in outpatients
4. No chronic illness that influences fertility (such as diabetes or autoimmune disorders)
5. Patient or authorised representative able to comprehend and sign the Informed Consent prior to enrolment in the study
6. BMI <35
7. Able and willing to use barrier contraception or abstain from sexual intercourse in the menstrual cycle of the trial period

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Pregnant, lactating, or planning pregnancy during the course of the trial
2. Hormonal treatment
3. Any concomitant medical treatment for or has any significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the trial, or may influence the result of the trial, or the participant's ability to participate in the trial
4. Allergy to anaesthetics (where applicable), silicone, or barium sulphate
5. Current ongoing investigations of abnormal uterine bleeding
6. Current, ongoing, or recurrent vaginal or pelvic infection
7. Body-worn life-sustaining electronic devices.
8. Abnormalities within the reproductive tract prohibiting the safe insertion of an intrauterine device

Date of first enrolment
22/07/2021

Date of final enrolment
28/02/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Southampton General Hospital
University Hospital Southampton NHS Foundation Trust
Mailpoint 18
Tremona Road
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No