ISRCTN85528745 https://doi.org/10.1186/ISRCTN85528745

The intrauterine environment during the luteal phase of the menstrual cycle

Submission date
30/01/2026

Recruitment status
No longer recruiting

Registration date
30/01/2026

Overall study status
Completed

Last Edited
30/01/2026

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
Embryo implantation often fails in in vitro fertilization (IVF) treatments, depending on both embryo quality and endometrial receptivity. Nowadays, high-quality embryos can be produced and selected, but the uterine readiness for embryo implantation is a long-overlooked need in the field. We want to collect first-human data of the intrauterine oxygenation profiles of women during their menstrual cycles, to study if this parameter could be useful to assess endometrial receptivity.

Who can participate?
Healthy volunteers aged between 18 and 35 years with regular menstrual cycles

What does the study involve?
At-home daily urine testing for a week, around 6-7 visits for intrauterine measurement, vaginal ultrasound and blood analysis.

What are the possible benefits and risks of participating?
Participants will not directly benefit from taking part in this study. There is a small risk of infection because a catheter will be placed in the uterus. This risk will be kept as low as possible by using sterile equipment and clean procedures.

Where is the study run from?
Vall d'Hebron University Hospital (Spain)

When is the study starting and how long is it expected to run for?
January 2022 to June 2022

Who is funding the study?
1. The Vall d'Hebron Research Institute (Spain)
2. Manina Medtech SL (Spain)

Who is the main contact?
Dr Melchor Carbonell, melchor.carbonell@vallhebron.cat

Contact information

Type(s)
Principal investigator, Public

Contact name
Dr Melchor Carbonell

Contact details
Pg. de la Vall d'Hebron, 119, Horta-Guinardó
Barcelona
Spain
08035
+34 (0)934893177
melchor.carbonell@vallhebron.cat

Type(s)
Public, Scientific

Contact name
Ms Anna Teixidó

Contact details
Pg. de la Vall d'Hebron, 119, Horta-Guinardó
Barcelona
Spain
08035
+34 (0)934893177
anna.teixido@vallhebron.cat

Type(s)
Scientific

Contact name
Dr Monica Rodriguez de La Vega

Contact details
Bruc 35 4-2A
Barcelona
Spain
08010
+34 (0)645433894
monica.delavega@maninamedtech.com

Additional identifiers

Study information

Scientific Title

The pattern of an intrauterine biophysical parameter as an indicator of the implantation window: a feasibility study

Acronym
PR(AMI)336/2021

Study objectives
To explore intrauterine oxygen patterns as a potential marker of endometrial readiness for embryo implantation.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 15/10/2021, Comité De Ética De Investigación Con Medicamentos Del Hospital Universitari Vall d'Hebron (Pg. de la Vall d'Hebron, 119, Horta-Guinardó, Barcelona, 08035, Spain; +34 (0)934893000; ceic@vhir.org), ref: PR(AMI)336/2021

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose
Basic science, Device feasibility

Study type(s)

Health condition(s) or problem(s) studied
Endometrial readiness for embryo implantation

Interventions
During the luteal phase in healthy volunteers, intrauterine oxygen pressure is measured every 48 hours using the methodology described by Otossen et al. in "Observations on intrauterine oxygen tension measured by fibre-optic microsensors". Reproductive BioMedicine Online, 2006, 13(3), 380–385

The study also includes blood sampling and transvaginal ultrasound.

Intervention Type
Device

Phase
Not Applicable

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

Primary outcome(s)
1. Intrauterine oxygen pattern measured using optical sensor at every 48 h after luteinizing hormone (LH) surge

Key secondary outcome(s))

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. Female
2. Healthy
3. 18-35 years old
4. Regular menstrual cycles
5. BMI below 30 kg/m2

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
Female

Total final enrolment
8

Key exclusion criteria
1. Medical pathology: insulin-dependent diabetes mellitus, Cushing’s syndrome, uncontrolled thyroid dysfunction, hepatic and/or renal insufficiency, any condition contraindicating ovarian stimulation and/or pregnancy, antiphospholipid syndrome
2. Uterine pathology: endometriosis, uterine cancer, congenital malformations, endometrial polyps, uterine fibroids
3. Current smoker

4. Use of oral contraceptives or intrauterine device within the last 3 months
5. Inadequate understanding (oral and written) of the Spanish language

Date of first enrolment
10/01/2022

Date of final enrolment
01/06/2022

Locations

Countries of recruitment
Spain

Study participating centre
Vall d'Hebron University Hospital
Pg. de la Vall d'Hebron, 119, Horta-Guinardó
Barcelona
Spain
08035

Sponsor information

Organisation
Vall d´Hebron Research Institute

Organisation
Manina Medtech SL

Funder(s)

Funder type

Funder Name
Vall d´Hebron Research Institute

Funder Name
Manina Medtech SL

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available