

The intrauterine environment during the luteal phase of the menstrual cycle

Submission date 30/01/2026	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/01/2026	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 05/05/2026	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

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

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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**

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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2026	05/05/2026	Yes	No