

# Study to evaluate if the uterus is ready for embryo implantation in in vitro fertilization treatments

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<b>Registration date</b> 09/10/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 09/10/2025	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

In vitro fertilization (IVF) success rates remain below 40%, with embryo transfer being a leading cause of failure. This study aims to evaluate whether the concentration of a biomarker dissolved in uterine fluid (alone or in combination with other clinical data) can predict the outcome of embryo transfer to improve success rates.

### Who can participate?

Female IVF patients aged 18-42 years undergoing frozen embryo transfer

### What does the study involve?

A measurement of a biomarker dissolved in endometrial fluid is conducted on the day of embryo transfer using the investigational device Seedchrony (RUO 02). The measurement results are hidden to both investigators and participants and do not influence clinical decision-making.

### What are the possible benefits and risks of participating?

Participation offers no direct personal benefit, but it may help develop a device to assess uterine readiness for embryo implantation on transfer day, informing whether to proceed or defer the transfer to improve IVF success and reduce attempts. Risks are similar to standard embryo transfer: possible mild discomfort from the catheter (reduced by arriving with a full bladder) and a small risk of bleeding or infection, kept less than 0.1% with sterile technique.

### Where is the study run from?

Vall d'Hebron Research Institute (VHIR) and Manina Medtech SL (Spain)

### When is the study starting and how long is it expected to run for?

July 2025 to July 2026

Who is funding the study?

In addition to private funding from Manina Medtech, this study is supported by the project CPP2022-009720, funded by the Spanish State Research Agency (AEI), and co-financed by the European Union through NextGenerationEU/PRTR.

Who is the main contact?

Dr Gina Abello Sumpsi, gina.abello@maninamedtech.com

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

R010203\_PG20-01\_Seedchrony03\_PIC, CPP2022-009720

## Study information

### Scientific Title

Clinical research to estimate the predictive capacity of SEEDCHRONY on the success of the cryotransfer with a single euploid blastocyst: Seedchrony03

### Acronym

Seedchrony03

### Study objectives

The objective of this investigation is to assess whether the concentration of an intrauterine biomarker (alone or in combination with other embryo and patient clinical variables), measured on the day of embryo transfer, can predict embryo transfer outcomes.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 18/07/2025, Ethics board from the University Hospital Vall d'Hebron (VHIR Edifici Central, Pg. de la Vall d'Hebron, 129, Horta-Guinardo, Barcelona, 08035, Spain; +34 (0) 934893000; ceic@vhir.org), ref: PS(AG)029/2025(6480)

### Study design

Exploratory open-label single-arm multicenter study

### Primary study design

Interventional

### Study type(s)

Safety, Efficacy

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

Uterine readiness for embryo transfer in IVF patients undergoing euploid blastocyst transfer

### Interventions

An intrauterine measurement of a biomarker dissolved in endometrial fluid will be conducted on the day of embryo transfer using the investigational device Seedchrony (RUO). This device incorporates a microsensor within a guiding catheter to quantify biomarker levels in uterine fluid

entering the catheter. The measurement procedure lasts approximately 2 minutes. A blood sample will also be collected on the day of embryo transfer for biomarker analysis.

## **Intervention Type**

Device

## **Phase**

Not Applicable

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

Seedchrony RUO 02

## **Primary outcome(s)**

1. Concentration of a biomarker dissolved in the endometrial fluid measured using the medical device Seedchrony (RUO 02) during 2 minutes on the embryo transfer day.
2. Clinical pregnancy outcome assessed by ultrasound at post-transfer week 4. Results will be record as positive or negative.

## **Key secondary outcome(s)**

1. Biochemical pregnancy outcome assessed using a serum  $\beta$ -hCG (pregnancy) test conducted 10–14 days after embryo transfer. The result will be recorded as positive or negative
2. Seedchrony algorithm accuracy calculated as the proportion of correct predictions (true positives + true negatives) by the total number of predictions
3. Seedchrony algorithm sensitivity calculated as the number of true positives divided by the total number of actual positives (true positives + false negatives)
4. Seedchrony algorithm specificity calculated as the number of true negatives divided by the total number of actual negatives (true negatives + false positives)
5. Pain measured using the visual analogue score (VAS) after intrauterine biomarker measurement
6. End-user experience assessed through a short questionnaire administrated after every intrauterine measurement
7. Seedchrony performance evaluated by recording and reporting any erroneous readings, device malfunctions or software failures observed during the trial
8. Seedchrony safety monitored by reporting adverse events and serious adverse events related to the investigational device during the trial, as well as any operational or safety incidents not previously identified in earlier studies or risk analyses

## **Completion date**

31/07/2026

## **Eligibility**

### **Key inclusion criteria**

1. Patients who have signed the informed consent form
2. Patients with a body mass index (BMI)  $\leq 30$  kg/m<sup>2</sup>
3. Patients undergoing their first transfer cycle with a vitrified euploid blastocyst selected according to PGT-A
4. Patients eligible for a modified natural transfer cycle with ovulation trigger and luteal phase support
5. Patients with an endometrial thickness  $\geq 7$  mm and a trilaminar pattern on the day of the trigger visit

6. Patients scheduled for a single embryo transfer of a day 5 euploid blastocyst
7. Patients scheduled to undergo embryo transfer after 120 hours of progesterone exposure

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

42 years

**Sex**

Female

**Key exclusion criteria**

1. Patients with a prior history of repeated pregnancy loss (two or more miscarriages).
2. Patients with a prior history of recurrent implantation failure (RIF), defined as failure of three or more transfers with A/B-quality embryos from at least two different cycles, or failure of one or more transfers with a euploid embryo.
3. Use of sperm obtained from a testicular biopsy.
4. Patients diagnosed with at least one of the following medical conditions: insulin-dependent diabetes mellitus, Cushing's syndrome, uncorrected thyroid dysfunction, liver and/or kidney failure, or antiphospholipid syndrome.
5. Patients currently taking any anti-inflammatory drugs that may influence prostaglandin production (e.g., ibuprofen, naproxen, indomethacin, mesalazine).
6. Lack of adequate understanding, oral or written, of the clinical research protocol and informed consent form.

**Date of first enrolment**

27/10/2025

**Date of final enrolment**

23/03/2026

**Locations****Countries of recruitment**

Spain

**Study participating centre**

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**Study participating centre**

**Eugin Barcelona**

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**Study participating centre**

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**Study participating centre**

**Instituto Bernabeu Palma de Mallorca**

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## **Sponsor information**

**Organisation**

Manina Medtech

**Organisation**

Vall d'Hebron Institut de Recerca

**ROR**

<https://ror.org/01d5vx451>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Agencia Estatal de Investigación

**Alternative Name(s)**  
Spanish State Research Agency, Spanish Agencia Estatal de Investigación, AEI

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
Spain

**Funder Name**  
European Union

**Funder Name**  
Manina Medtech

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during this clinical investigation will remain confidential and will not be publicly shared, as they contain proprietary information subject to intellectual property protection. Following publication of the study findings, summary analyses and integrated data will be made available, but access to raw datasets will be restricted to ensure data integrity and protection of trade secrets.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes