ISRCTN11352119 https://doi.org/10.1186/ISRCTN11352119

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

Submission date
06/10/2025

Recruitment status
Recruiting

Registration date
09/10/2025

Overall study status
Ongoing

Last Edited
09/10/2025

Condition category
Pregnancy and Childbirth

[X] 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
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

Contact information

Type(s)
Principal investigator

Contact name
Dr Melchor Carbonell

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

Type(s)
Public

Contact name
Dr Gina Abelló

Contact details
Carrer de la Llacuna, 162-164
Barcelona
Spain
08018
+34 (0)934 34 11 69
gina.abello@maninamedtech.com

Type(s)
Scientific

Contact name
Dr Monica Rodriguez de la Vega

Contact details
Carrer de la Llacuna, 162-164
Barcelona
Spain

08018
+34 (0)934 34 11 69
monica.delavega@maninamedtech.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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 β-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) ≤30 kg/m²
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 ≥ 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
CRA Barcelona
Carrer del Mestre Nicolau, 9, Sarrià-Sant Gervasi
Barcelona
Spain
08021

Study participating centre
Eugin Barcelona
Carrer de Balmes, 236, Sarrià-Sant Gervasi
Barcelona
Spain
08006

Study participating centre
CIRH
Carrer de Balmes, 236, Sarrià-Sant Gervasi
Barcelona
Spain
08006

Study participating centre
Instituto Bernabeu Palma de Mallorca
C/ Aragó, 8, Llevant
Palma Mallorca
Spain
07006

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?
Study website	Study website	11/11/2025	11/11/2025	No	Yes