

GLOBAL RANDOMIZED CONTROLLED TRIAL (RCT) FOR VALIDATION OF ORA

Description:

This study aims to validate ORA, a non-invasive endometrial receptivity test utilizing microRNA biomarkers in the blood. ORA accurately identifies a patient's window of implantation, informing the timing of personalized embryo transfer.

Status:

Ongoing

Study Objective:

Our primary objective is to demonstrate the clinical benefit of ORA™ in enhancing implantation success rates in eligible patients with a history of failed implantation.

Patient Criteria

- History of at least one implantation failure with a low mosaic/euploid embryo
- Patients aged between 28-45 years
- At least one euploid embryo available for transfer
- BMI less than 30

Trial Design

- Patient Recruitment and Enrollment: We recruit and enroll patients based on the above criteria.
- Randomization: All subjects are randomized into two sub-groups:

- Receptivity-Timed Group: Frozen embryo transfer is performed based on receptivity timing results of ORA™.
- Standard Group: Frozen embryo transfer is performed based on the standard cycle. A blood draw taken on the same day as the embryo transfer is later analyzed by ORA™ to validate receptivity window.

Clinical Impact

By leveraging ORA™'s advanced technology, we strive to enhance ART success rates and improve patient outcomes. The results of the trial will be published, with authorship order based on the contribution of individual sites. In addition to sponsoring the ORA™ tests, we are providing additional incentives to patients, principal investigators, and sites to support the trial.