

# Non-Invasive Assessment of Endometrial Receptivity Using ora<sup>®</sup> Enhances IVF Success: A Randomized Controlled Study

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## 1 Background & Aims

Endometrial receptivity is critical for embryo implantation, yet the window of implantation (WOI) varies among individuals. Conventional biopsy-based tests are invasive and may affect patient compliance and reproducibility. This study evaluated ora<sup>®</sup>, a noninvasive blood-based assay that analyzes circulating microRNAs to identify each patient's WOI and enhance in vitro fertilization (IVF) outcomes.

## 2 Method

In this randomized controlled trial, women undergoing frozen embryo transfer (FET) were assigned to either a control group (standard transfer timing) or an ora<sup>®</sup>-guided group (personalized timing based on ora<sup>®</sup> results). Eligible participants had prior implantation failure after euploid or low-mosaic embryo transfer and no ovarian, uterine, or tubal disorders. In the ora<sup>®</sup> group, blood samples were collected during a mock cycle to determine individualized WOI, followed by embryo transfer at the recommended time. The primary endpoint was clinical pregnancy rate.

## 4 Conclusion

This ongoing randomized controlled trial demonstrates that ora<sup>®</sup>, a noninvasive miRNA-based test, can improve clinical pregnancy rates in patients with previous implantation failure of euploid or low-mosaic embryo transfer. By identifying individualized WOI through circulating biomarkers, ora<sup>®</sup> offers a reproducible and patient-friendly alternative to biopsy-based assessments. Additionally, only about 15% of patients showed a displaced WOI, a lower rate than reported with invasive methods.

## 3 Results

A total of 87 patients met inclusion criteria. The clinical pregnancy rate was higher in the ora<sup>®</sup>-guided group (66.7%) than in the control group (47.9%), indicating improved synchronization of embryo transfer with endometrial receptivity. Of the 87 patients, 13 (15%) had a displaced WOI. In the control arm, 6 patients with a displaced WOI achieved a 16.7% pregnancy rate at the standard time. In contrast, in the ora<sup>®</sup> arm, 7 patients with a displaced WOI who transferred at the suggested time of 144 hours achieved a 71.4% rate.

|                    | Excluding Specific Diagnoses<br>(Uterine Fibroids, Ovarian Disorders, PCOS, Tubal Factor) |               |
|--------------------|---|---------------|
| Clinical Pregnancy | Control   | Study         |
| Yes                | 23<br>(47.9%)   | 26<br>(66.7%) |
| No                 | 25  | 13            |
| Total Number       | 48  | 39            |
|                    | 87  |               |