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TITLE

A RANDOMIZED, DOUBLE-BLIND, DOUBLE-DUMMY, TWO-ARM, MULTICENTER PHASE III STUDY COMPARING THE EFFICACY, SAFETY AND TOLERABILITY OF ORAL DYDROGESTERONE 30 MG DAILY (10 MG TID) VERSUS INTRAVAGINAL MICRONIZED PROGESTERONE 600 MG DAILY (200 MG TID) FOR LUTEAL SUPPORT IN IN-VITRO FERTILIZATION (LOTUS I STUDY)

AUTHORS

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ABSTRACT

Context

Routine practice in most IVF clinics is the use of micronized vaginal progesterone (MVP) for luteal phase support in IVF cycles. The side effects and inconvenience associated with vaginal application indicate a need for an effective, patient-friendly, well-tolerated alternative to MVP.

Objective

To compare the efficacy and safety of oral dydrogesterone versus MVP.

Methods

Double-blind, double-dummy, randomized, two-arm, multicenter non-inferiority study.

Patient(s)

Premenopausal women undergoing IVF treatment.

Intervention(s)

Subjects were randomized to receive either oral dydrogesterone 10 mg or MVP 200 mg three times daily. Luteal support started on day of oocyte retrieval and continued for up to 10 weeks, or for as long as pregnancy continued.

Main outcome measure(s)

Primary objective was presence of fetal heart beats at pregnancy week 10 (12 weeks of gestation).

Result(s)

497 and 477 subjects randomized to dydrogesterone and MVP groups, respectively, were included in the full analysis sample (FAS); 492 and 475 subjects, respectively, were included in the per protocol subject (PPS) sample. FAS and PPS results were similar throughout. In the FAS, the difference in pregnancy rate at 10 weeks (12 weeks gestation) was 4.7% in favor of dydrogesterone (95% CI –1.2% to 10.6%), demonstrating non-inferiority to MVP. Live birth rates were 34.6% (172/497) and 29.8% (142/477) in the dydrogesterone and MVP groups, respectively. Safety and tolerability profiles of dydrogesterone and MVP were similar.

Conclusions

Oral dydrogesterone was demonstrated to be clinically as efficacious as MVP and showed a similar

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safety profile in the study. Due to its patient-friendly and convenient administration, dydrogesterone may therefore replace MVP as the standard of care for luteal phase support in IVF.