

should be performed to evaluate for other contributing factors to this difference in implantation rates and continued development of the blastocyst to demonstrate positive fetal cardiac activity. This includes adjusting for maternal age, transfer protocol, endometrial receptivity, and methods of luteal support.

Supported by: None to disclose.

O-101 Tuesday, October 9, 2018 11:45 AM

A PLACEBO-CONTROLLED, RANDOMIZED, DOUBLE-BLIND, PHASE 3 STUDY ASSESSING ONGOING PREGNANCY RATES AFTER SINGLE ORAL ADMINISTRATION OF A NOVEL OXYTOCIN RECEPTOR ANTAGONIST, NOLASIBAN, PRIOR TO SINGLE EMBRYO TRANSFER. H. Visnova,^a H. J. Tournaye,^b A. Humberstone,^c P. Terrill,^d L. Macgregor,^e E. Loumaye.^e ^aIVF CUBE, SAR CGPS, Prague, Czech Republic; ^bCRG, Brussels, Belgium; ^cObsEva SA, Geneva, Switzerland; ^dCytel UK, London, United Kingdom.



OBJECTIVE: The objective of the study was to confirm whether administration of a single oral 900 mg dose of nolasiban, prior to day 3 or 5 (D3, D5) fresh single embryo transfer (SET) improves ongoing pregnancy rate.

DESIGN: Multinational, prospective, double-blind, randomized, parallel group, placebo-controlled, Phase 3 study assessing a single oral 900 mg dose of nolasiban or placebo (1:1), administered about 4 hours before ET following IVF/ICSI. The primary endpoint was an ongoing pregnancy defined as ultrasound observation of a fetal heartbeat at 10 weeks post-ET. Secondary endpoints included clinical pregnancy at 6 week post-ET and miscarriage.

MATERIALS AND METHODS: 778 subjects were recruited from 41 fertility clinics in Europe from Mar-Oct 2017. Eligibility criteria included age ≤ 36 years, ≤ 1 failed ART cycle, use of a GnRH antagonist, < 1.5 ng/mL serum progesterone on the day of hCG, and luteal support with vaginal micronized progesterone. One good quality embryo was transferred on either D3 (n=388) or D5 (n=390). The primary analysis was performed on the pooled D3/D5 population. Subgroup analyses were performed on the D3 and D5 populations separately. Data are reported up to 10 weeks post-ET. Follow-up of pregnancy, delivery including live birth, and neonatal and infant outcomes up to 6 months after birth is ongoing.

RESULTS: The ongoing pregnancy rates at week 10 in the pooled D3/D5 population were 29% for placebo and 36% for nolasiban (p=0.031); a 25% relative increase. The difference was more pronounced in the D5 subgroup (placebo 35%, nolasiban 46%; p=0.034, a 32% relative increase), compared to the D3 subgroup (placebo 22%, nolasiban 25%; p=0.477, a 14% relative increase). Demographics were generally comparable between treatment groups (e.g. mean age 31; BMI 24; No. oocytes retrieved 9-10; No. good quality embryos 2.5-2.6, serum progesterone prior to ET). Sub-group analyses of these baseline factors did not show any significant interaction with the effect of nolasiban. Single dose administration of 900 mg nolasiban was well tolerated and did not result in increased occurrence of adverse events compared to placebo. The overall safety profile of nolasiban was similar to placebo.

CONCLUSIONS: A single oral dose of nolasiban taken before fresh SET resulted in a relative 25% increase in ongoing pregnancy rate compared to placebo. Nolasiban was well tolerated. The use of nolasiban has the potential to improve pregnancy and live birth rates following SET and potentially reduce the incidence of multiple pregnancies from ART by encouraging the use of elective SET.

References:

ClinicalTrials.gov: NCT03081208.

Supported by: The study was funded by ObsEva SA.

O-102 Tuesday, October 9, 2018 12:00 PM

INTENT TO TREAT ANALYSIS REVEALS SIGNIFICANTLY IMPROVED CLINICAL OUTCOMES WITH ANEUPLOIDY TESTING IN AN AGE-MATCHED POPULATION. M. Katz-Jaffe, E. Surrey, R. L. Gustofson, L. A. Kondapalli, S. Barton, L. Ehrhart, S. McCormick, W. B. Schoolcraft. Colorado Center for Reproductive Medicine, Lone Tree, CO.



OBJECTIVE: Preimplantation genetic testing for aneuploidy (PGT-A) has been proposed as an improved embryo selection strategy to decrease pregnancy loss and increase live birth rates for infertility patients undergoing

TABLE 1.

| FET Outcomes | Freeze All (n=40) | PGT-A (n=39) |
|--------------------------------------|-------------------|--------------|
| Implantation Rate (fetal heart tone) | 48.2% | 78.9%* |
| Ongoing Clinical Pregnancy Rate | 60% | 84.6%* |
| Miscarriage Rate | 16.7% | 6.1% |
| Live Birth Rate per FET | 50% | 79.5%* |
| Live Birth Rate per Intent to Treat | 43.5% | 65.2%* |

*P<0.05

in vitro fertilization (IVF). In an intent to treat analysis, we investigated clinical outcomes with PGT-A, compared to patients who have freeze-all blastocyst cycles with embryo selection based on morphology alone.

DESIGN: Prospective cohort age-matched study.

MATERIALS AND METHODS: Infertility couples were identified during their IVF consult as intent to treat with either a freeze-all blastocyst cycle or IVF with PGT-A. Female patients were maternally age-matched between the two treatment groups (mean 32.5 \pm 3.7 years; n=46 per group). For the 'Freeze All' group, blastocysts were vitrified using the Cryotop method on either day 5 (D5) or day 6 (D6) of development. In contrast, for the 'PGT-A' group, prior to vitrification, D5 or D6 blastocysts were biopsied and analyzed for chromosome numeration using the VeriSeq™ platform (Illumina). Standard protocols for a hormone replacement frozen embryo transfer (FET) were utilized, with either blastocyst morphology alone (Freeze All) or euploid (PGT-A) embryo selection. Primary outcomes measured included implantation (fetal heart tone), ongoing clinical pregnancy, miscarriage, and live birth rates. Statistical analysis included Student's t-test and Fisher's exact test where appropriate, significance at P<0.05.

RESULTS: In each treatment group, 46 retrievals were performed with no significant differences in number of oocytes retrieved, fertilized or number of usable blastocysts between the two treatment groups (P \geq 0.05; ns). Two retrievals (4.4%) resulted in no fertilization and four (8.7%) with no blastocyst development in the Freeze All group, while one (2.2%) resulted in no fertilization and four (8.7%) with no blastocyst development in the PGT-A group (P \geq 0.05; ns). Additionally, following PGT-A, two (4.4%) cycles ended with all aneuploid blastocysts. Remaining patients underwent FET with significant clinical improvements for primary outcomes measured in the PGT-A group (P<0.05; Table 1).

CONCLUSIONS: From the prospective of intent to treat analysis, at the time a clinical decision is made to proceed with IVF therapy, the inclusion of PGT-A resulted in significantly improved clinical outcomes in a younger maternally age-matched population. This data reflects that embryo selection incorporating PGT-A should be considered for infertility patients undergoing IVF.

CONTRACEPTION AND FAMILY PLANNING

O-103 Tuesday, October 9, 2018 10:45 AM

THE POWER OF POLICY: TRENDS IN EMERGENCY DEPARTMENT UTILIZATION FOR EMERGENCY CONTRACEPTION, 2006-2014. S. Chibber, R. Baker, E. Giuliani, D. Conway, V. K. Dalton, E. E. Marsh. Department of Obstetrics and Gynecology, University of Michigan, Ann Arbor, MI.



OBJECTIVE: To describe national trends in emergency department (ED) utilization for emergency contraception (EC) following the 2006 US Food and Drug Administration (FDA) approval of levonorgestrel EC without a prescription and coverage expansion for contraceptive services under the Affordable Care Act (ACA).

DESIGN: Retrospective cross-sectional study using a nationally-representative, all-payer database.

MATERIALS AND METHODS: ED utilization for EC was evaluated using the Nationwide Emergency Department Sample (NEDS), Healthcare Cost and Utilization Project (HCUP), Agency for Healthcare Research and Quality (AHRQ; Rockville, MD). The database was queried for women aged 15-44 yo who presented to the ED with "encounter for emergency contraception counseling and prescription" listed as their primary ICD-09 diagnosis (V25.03). The primary outcome was the number of annual ED visits made between 2006-2014. Parameters assessed included age, payer