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**IMPACT OF SERUM PROGESTERONE LEVELS ON THE DAY OF EMBRYO TRANSFER IN ARTIFICIAL ENDOMETRIAL PREPARATION CYCLES ON THE ONGOING PREGNANCY RATE. AN INTERIM ANALYSIS.**

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**OBJECTIVE:** To analyze the relationship between serum progesterone (P) the day of embryo transfer and Ongoing pregnancy rates (OPR) in artificial endometrial preparation cycles.

**DESIGN:** Single center prospective cohort study including infertile patients undergoing embryo transfer after an artificial endometrial preparation cycle with estradiol valerianate and vaginal micronized progesterone (400 mg/12 hours). Sample size ( $n=1197$ ) was calculated to detect a 10% difference in OPR (40-50%) between 2 groups ( $P < P_{25}$  or  $P > P_{25}$ ) according to serum P levels, in a two-sided test with a statistical power of 80% and a confidence level of 95%. This is an interim analysis of the 50% of the sample ( $n=599$ ) which includes all patients recruited from September 12th, 2017 to March 15th, [2018.ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03272412) Identifier: NCT03272412.

**MATERIALS AND METHODS:** Patients undergoing embryo transfer in the context of an artificial endometrial preparation cycle, either with own or donor eggs, aged  $<50$ , BMI  $<30$  Kg/m<sup>2</sup>, with a normal uterine cavity in 2D ultrasound, a triple layer endometrium  $>6.5$  mm; in a private infertility center. Serum P determination was performed the day of embryo transfer. Primary endpoint was ongoing pregnancy rate at the time of abstract submission ( $>9$  weeks for the last cases included).

**RESULTS:** Of 599 patients recruited, 542 fulfilled all the inclusion/exclusion criteria. Reasons for exclusion were: changes of doses or ways of administration of progesterone. The mean age of the included women was  $39.8 \pm 4.5$ ; BMI:  $23.7 \pm 4.3$ ; Endometrial thickness:  $8.7 \pm 1.6$  mm. Mean serum P the day of embryo transfer was  $12.0 \pm 6.2$  ng/ml (p<sub>25</sub>: 8.0; p<sub>50</sub>: 11.2; p<sub>75</sub>: 14.8). The ongoing pregnancy rates according to serum P levels were:  $<p_{25}$ : 35.8%; p<sub>25</sub>-P<sub>50</sub>: 46.2%; p<sub>50</sub>-P<sub>75</sub>: 57.0%;  $>p_{75}$ : 55.1%. Women with serum P  $<8.0$  ng/mL (p<sub>25</sub>) had a significantly lower ongoing pregnancy rate compared to the rest of patients: 35.8% vs. 52.8%;  $p < 0.001$ . Clinical pregnancy rate was 47.0% vs. 60.1% ( $p < 0.008$ ) and pregnancy loss rate (including biochemical and clinical miscarriages) was 36.0% vs. 19.4% ( $p < 0.008$ ). The ROC curve showed a significant predictive value of serum P levels on the day of embryo transfer for OPR, with an AUC of (95% CI)  $0.59$  (0.55-0.64),  $p < 0.000$ .

**CONCLUSIONS:** The results of the present study suggest that there is a minimal threshold of serum P values the day of embryo transfer that needs to be reached in artificial endometrial

preparation cycles to optimize the pregnancy outcome. We cannot extrapolate these findings when using other ways of progesterone administration.