CONCLUSIONS: Women with a diagnosis of RA or SLE have a higher risk of unexplained infertility compared to women who did not have RA or SLE. Future studies will elucidate the mitigating effects of ethnicity among RA patients and insurance status among SLE patients.

SUPPORT: None

O-196 10:25 AM Tuesday, October 20, 2020

CHARACTERIZATION OF PITUITARY AND OVARIAN HORMONE CONCENTRATIONS DURING TREATMENT WITH RELUGOLIX COMBINATION THERAPY. Ingrid Duijkers, MD, PhD,1 Elizabeth M. Migoya, Pharm D,2 Juan Camilo Arjona Ferreida, MD,1 Christine Klipping, MD, PhD1 1dinoxx consultancy bv, Groningen, Netherlands; 2Myovant Sciences Inc., Brisbane, CA; 1Chief Medical Officer, Brisbane, CA; 2Dinox BV, Berlin, Germany.

OBJECTIVE: To characterize the effects of Relugolix combination therapy (Rel-CT; relugolix 40 mg, estradiol [E2] 1 mg, norethindrone acetate 0.5 mg) on pituitary (lutecinizing hormone [LH] and follicle-stimulating hormone [FSH]) and follicular (E2 and progesterone [P]) hormone concentrations, follicular growth, and endometrial thickness.

DESIGN: An open-label, single-cohort study. Healthy, premenopausal, ovulatory women (n=70) received oral administration of Rel-CT once daily for 84 days.

MATERIALS AND METHODS: Blood samples for determination of LH, FSH, E2, and P serum concentrations were collected every 3 (±1) days during the treatment and post-treatment periods. LH, FSH and P were quantified using a validated, enzyme-linked immunosorbent assay. E2 serum concentrations were quantified using a validated liquid chromatography-tandem mass spectrometry method. The size of the dominant follicle and endometrial thickness were measured by transvaginal ultrasound performed every 3 (±1) days during the treatment and post-treatment periods.

RESULTS: Relugolix, an orally active, potent, non-peptide gonadotropin-releasing hormone (GnRH) receptor antagonist, blocks endogenous GnRH from binding to GnRH receptors, preventing the release of LH and FSH from the anterior pituitary gland. Reduction in FSH minimizes follicular growth and development, with consequently lower production of E2. In the absence of an LH surge, and ovulation, the corpus luteum does not develop, resulting in decreased production of P. In the current study, during treatment with Rel-CT, mean LH concentrations were below 1.0 U/L, and FSH concentrations were suppressed, being maintained between 2 and 3 U/L, with an absence of pre-ovulatory peaks. Follicular growth was diminished, with a mean dominant follicle size consistently at approximately 6 mm. Mean (median) E2 concentrations were maintained between 32.6 and 44.5 pg/mL (30.6 and 40.1 pg/mL), comparable to concentrations in the early follicular phase of the menstrual cycle, as a result of profound suppression of ovarian E2 production and exogenous administration of E2 as part of Rel-CT. Endometrial proliferation was markedly suppressed, with mean endometrial thickness between 4 and 5 mm. Mean P concentrations remained between 1 and 1.3 nmol/L with individual concentrations below 5 nmol/L (corresponding to 1.57 ng/mL), reflecting an absence of luteal activity. Over 84 days, Rel-CT inhibited ovulation in 100% of women.

CONCLUSIONS: Rel-CT consistently suppressed pituitary and ovarian hormone concentrations, follicular growth and endometrial thickness. The reduction in systemic E2 and progesterone concentrations is expected to minimize hormone-induced growth and proliferation of uterine fibroids and endometriosis lesions, resulting in an improvement of disease-related symptoms without adverse consequences related to a hypoestrogenic state.

SUPPORT: Myovant Sciences Inc.

O-197 10:40 AM Tuesday, October 20, 2020

CELL-LEVEL EXPRESSION OF SARS-COV-2 CELL ENTRY FACTORS IN HUMAN ENDOMETRIUM DURING THE PRECONCEPTION PERIOD. Felipe Vilella, PhD,1 Wenxin Wang, PhD,2 Inmaculada Moreno, PhD,2 Stephen R. Quake, DPhil,2 Carlos Simon, MD, PhD1 1Igenomix Foundation, INCLIVA, Valencia, Spain, Department of Obstetrics and Gynecology, BIDMC, Harvard University, Boston, MA; USA; 2Northwestern University, Chicago, IL, 1Northwestern University, Chicago, IL; 2Northwestern Feinberg School of Medicine, Chicago, IL.

OBJECTIVE: To determine if the percentage of reproductive age women who are immune to measles is at or above the level required for herd immunity (95%) and to evaluate the patient characteristics and demographics that correlate with measles non-immunity.

DESIGN: Retrospective case control.

MATERIALS AND METHODS: A retrospective chart review of women seeking preconception and fertility care who underwent serum testing for measles, rubella, and/or varicella immunity between March 1, 2018 and May 1, 2020 were included in the analysis. Serum tests resulted as either immune, non-immune, or equivocal, as determined by serum IgG titer levels for the respective diseases. Women with equivocal results underwent further testing to quantitate titers and determine immunity.

RESULTS: Equivocal results that did not have follow-up testing were excluded from the final analysis. Clinical characteristics were collected on the women including age, BMI, parity, race, and ethnicity. Students t test and chi square tests were used for continuous and categorical outcomes. Multivariable logistic regression was performed to control for confounding. A post hoc power analysis was performed.

RESULTS: 3,235 women were included in the study. Of the 1,396 women tested for measles antibodies (n=1396), 20.1% were considered non-immune.

FERTILITY & STERILITY® e81