ASRM 2016
Scientific Abstracts to be presented at the 72nd Scientific Congress of the American Society for Reproductive Medicine, October 17-19, 2016, Salt Lake City, Utah.

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October 17-19, 2016
Salt Lake City, Utah

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**ACUPUNCTURE AND CLOMIPHENE FOR INFERTILITY IN THE POLYCYSTIC OVARY SYNDROME: A MULTICENTRE RANDOMIZED CONTROLLED TRIAL.** X. Wu, E. Stener-Victorin, J. Liu, T. Wu, E. Ng, R. S. Legro, H. Zhang. 1Department of Obstetrics and Gynecology, Heilongjiang University of Chinese Medicine, Harbin, China; 2Department of Physiology and Pharmacology, Karolinska Institutet, Stockholm, Sweden; 3Centre for Evidence-Based Chinese Medicine, Beijing University of Chinese Medicine, Beijing, China; 4Chinese Clinical Trial Registry, Chinese Ethics Committee of Registering Clinical Trials, Chengdu, China; 5Department of Obstetrics and Gynecology, The University of Hong Kong, Hong Kong, China; 6Department of Obstetrics and Gynecology, Penn State University College of Medicine, Hershey, PA; 7Department of Biostatistics, Yale School of Public Health, New Haven, CT.

**OBJECTIVE:** To evaluate efficacy of live birth with acupuncture alone or combined with clomiphene to induce ovulation in infertile women with polycystic ovary syndrome (PCOS).

**DESIGN:** A double-blinded (clomiphene) and single blind (patients to type of acupuncture), multi-center (N=21 sites), 2x2 factorial trial.

**MATERIALS AND METHODS:** 1000 women with PCOS were randomly assigned in a 1:1:1:1 ratio, to receive acupuncture (active or control twice a week for 30 min per session) and medication (clomiphene or placebo for 5 days per cycle) for up to four cycles. The primary outcome measure was live birth, and ovulation was determined by weekly serum progesterone levels.

**RESULTS:** The live birth rates were significantly higher in the groups treated with clomiphene and acupuncture vs. placebo and acupuncture (P<0.015) with no interaction between type of acupuncture and medication: active treated vs clomiphene control (69 of 250 women [27.6%]), control acupuncture vs clomiphene group (66 of 250 [26.4%]) active acupuncture vs placebo (31 of 250 [12.4%]) and control acupuncture vs placebo group (39 of 250 [15.6%]). Ovulation rates were significantly higher in the two acupuncture arms compared to placebo arms. The rate of live births was significantly higher in women who ovulated and were treated with control acupuncture and clomiphene than those treated with active acupuncture and placebo (6 of 223 [2.7%] vs. 0 of 161 [0.0%], P<0.05). Clomiphene was associated with more dysmenorrhea and less abnormal vaginal bleeding, and active acupuncture was associated with more bruising and diarrhea.

**CONCLUSIONS:** Clomiphene was twice as effective at achieving live birth than placebo with no effect of acupuncture alone or in combination. These findings do not support acupuncture as an infertility treatment in women with PCOS. [ClinicalTrials.gov number, NCT01573858].

**References:**


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**ALLOGENEIC TRANSPLANTATION OF OVARIAN TISSUE WITH SOLE USE OF NOVEL IMMUNOMODULATOR, PREIMPLANTATION FACTOR (PIF), RESTORED OVAIRAN FUNCTION IN BABBONS.** M. Feichtinger, E. R. Barnea, A. Nyachier, M. Brannstrom, S. Kim, Roberta M. Muir, D. Wells, T. Huang. 1Department of Obstetrics and Gynecology, Medical University of Vienna, Vienna, Austria; 2Wunschbabby Institut Feichtinger, Vienna, Austria; 3BioIncept LLC, Cherry Hill, NJ; 4SIEP – Society for the Investigation of Early Pregnancy, Cherry Hill, NJ; 5Institute of Primate Research (IPR), Karen, Nairobi, Kenya; 6University of Gothenburg, Gothenburg, Sweden; 7University of Kansas, Kansas City, KS; 8American-Sino Women’s and Children’s Hospital, Shanghai, China.

**OBJECTIVE:** Although allo-transplantation of ovarian tissue can be a useful option for women with premature ovarian failure, immune rejection has been a big barrier for clinical application. PIF is an endogenous immunomodulator that regulates transplant acceptance. The study objectives are to a) evaluate the feasibility of ovarian allo-transplantation for restoration of ovarian function and b) assess the efficacy of synthetic PIF as sole immune acceptance regimen.

**DESIGN:** Experimental animal study on non-human primates (Papio anubis).

**MATERIALS AND METHODS:** After obtaining IACUC approval two female olive baboons with regular cycles were prepared for allogenic orthotopic ovarian transplantation. PIF was administered (10mg, twice a day, subcutaneously) as a sole agent to prevent immune rejection starting from one day before surgery. The animals underwent bilateral oophorectomy followed by transplantation of prepared ovarian cortex from the other animal. Postoperatively, animals were monitored for clinical and biochemical signs of graft rejection and return of ovarian function (perineal swelling followed by menstruation). Blood samples were obtained weekly for surveillance of rejection and of endocrine function.

**RESULTS:** Postoperatively, there were no clinical signs of rejection (vital signs, weight, urine output and skin change). Laboratory parameters (ALT, AST, BUN, creatinine) did not indicate organ rejection at any stage of the experiment. Histology of ovarian tissue before grafting showed multiple follicles. Serum FSH, E2 and progesterone levels showed ovarian failure after grafting. Seven months after transplantation, one animal restored ovarian function (evidenced by perineal swelling and return of menstruation).

**CONCLUSIONS:** Organ rejection was prevented by a novel immunomodulator PIF (without side effects) after allogeneic ovarian transplantation in baboons. In addition, our study showed the clinical feasibility of ovarian allo-transplantation. Importantly, the study showed the PIF effectiveness for restoration of ovarian function and fertility.

**Supported by:** This study was funded by the Medical Scientific Fund of the Mayor of Vienna (Nr: 14043), the Wunschbabby Institut Feichtinger, by an unrestricted grant from BioIncept and by private funds of M.F. and S.S.K.
RESULTS: Five MII oocytes with birefringent spindles were subjected to meiotic SNT. The 5 oocytes were successfully reconstituted and fertilized normally by ICSI. Four out of 5 fertilized oocytes developed into blastocysts. PGS showed that one blastocyst was euploid (46XY), while 3 embryos were aneuploid. The average transmission rate of maternal mtDNA in the biopsied euploid blastocyst was 5.10 ± 1.11% and the heteroplasmy level for 8993T>G was 5.73%. Transfer of the euploid embryo resulted in an uneventful pregnancy with delivery of a healthy boy at 37 weeks of gestation. The average level of transmitted mother’s mtDNA in several neonatal tissues including buccal epithelium, hair follicles, circumcised foreskin, urine precipitate, placenta, amnion, umbilical blood, and umbilical cord was less than 1.0 ± 0.92%. The baby is currently 3 months old and doing well.

CONCLUSIONS: Human oocytes reconstituted by SNT are capable of producing a healthy live birth. SNT may provide a novel treatment option in minimizing pathogenic mtDNA transmission from mothers to their babies.

References:

FREEZE-ALL VERSUS FRESH EMBRYO TRANSFER IN IVF/ICSI, A RANDOMISED CONTROLLED TRIAL (NCT02471573). L. T. Vuong, V. Q. Dang, T. M. Ho, B. G. Huynh, D. T. Ha, T. D. Pham, L. K. Nguyen, R. J. Norman, B. W. Mol, Ob/Gyn, University of Medicine and Pharmacy at Ho Chi Minh City, Ho Chi Minh City, Vietnam; Research Center for Genetics and Reproductive Health, School of Medicine, Vietnam National University Ho Chi Minh City, Ho Chi Minh City, Vietnam; IVFMD, My Duc hospital, Ho Chi Minh, Vietnam; Intensive Care Unit, national hospital of can tho, can tho, Vietnam; Robinson Research Institute, University of Adelaide, Trammere, Australia; Obstetrics & Gynecology, The University of Adelaide, North Adelaide, Australia.

OBJECTIVE: A growing body of evidence suggests that in women undergoing IVF/ICSI frozen embryo-transfer (ET) is superior to fresh ET. However, this hypothesis is not tested in large randomized controlled clinical trials (RCT). We performed a RCT comparing the effectiveness of frozen versus fresh ET in infertile women undergoing IVF/ICSI.

DESIGN: RCT in My Duc Hospital, Vietnam.

MATERIALS AND METHODS: We studied infertile couples undergoing their first or second IVF/ICSI cycle. Women with PCOS were excluded. All participants were treated with a gonadotropin-releasing antagonist protocol. Couples were eligible if at day 3 at least 1 high quality embryo was present. After informed consent, couples were randomised to a freeze-all or fresh ET strategy. In the freeze-all group, all grade 1 and 2 embryos were cryopreserved and then thawed on the day of ET in the following manipulated cycle. In the fresh ET group, a maximum of two fresh embryos were transferred in the stimulated cycle. The primary endpoint was ongoing pregnancy. Analysis was by intention-to-treat. We planned a marker analysis for endometrial thickness and serum progesterone.

RESULTS: Baseline characteristics were comparable. The primary endpoint ongoing pregnancy occurred in 36.3% versus 34.5% (RR 1.05 (0.87, 1.27)). Pregnancy rates, clinical outcomes and rates of treatment complications or adverse events were also comparable (see table). There was no significant interaction between both endometrial thickness (p = 0.101) and progesterone (p = 0.109) and the treatment effect.

CONCLUSIONS: In non-PCOS infertile couples undergoing IVF/ICSI, a freeze-all ET strategy did not improve the ongoing pregnancy rate as compared to a fresh ET strategy.

Supported by: Research Center for Genetics and Reproductive Health, School of Medicine, Vietnam National University, Ho Chi Minh City, Vietnam

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OBJECTIVE: To assess the efficacy and safety of UPA vs placebo in achieving amenorrhea and improving activity score.

METHODS: This was a phase 3, prospective, randomized, double-blind study (VENUS-I; NCT02147197). Subjects were randomized 1:1:1 to UPA 10 mg, UPA 5 mg, or placebo once daily for 12 weeks, with an additional 1 week of placebo before endpoint assessment (EOT/Day 84). Activity score was assessed by the revised activity subscale of the UF symptom health related quality of life questionnaire. Safety was assessed via adverse events (AEs) and endometrial biopsies.

RESULTS: Of 157 patients randomized (48 UPA 10 mg, 53 UPA 5 mg, 56 placebo), 69% were Black. Significantly more patients achieved amenorrhea for ≥35 consecutive days before EOT/Day 84 with UPA 10 mg (58.3%; p < 0.0001) and UPA 5 mg (47.2%; p < 0.0001) vs placebo (1.8%). The hazard ratio (HR) versus placebo for achieving amenorrhea at any time was significantly less with UPA 10 mg (49.1; p < 0.0001) and UPA 5 mg (35.5, p < 0.0001). Least squares mean change in activity score was significantly greater with UPA 10 mg (57.1% [5/6 reported hypertension at baseline] vs n=0), blood creatinine phosphokinase increased (5 vs 0), hot flush (5 vs 0), acne (3 vs 1), and nausea (2 vs 0). No treatment-related serious AEs or deaths were reported. No patients discontinued UPA due to AEs. No malignancies or endometrial atypical hyperplasia were reported.

CONCLUSIONS: In this US-based study, UPA was superior to placebo in rate of and time to amenorrhea. UPA also significantly improved patients’ activity scores and was well tolerated.

Supported by: Supported by Allergan plc