Study Article # 5

Reference: Zheng, C.H., Zhang, J., Wu, J., & Zhang, M.. (2014, May 9). The effect of transcutaneous electrical acupoint stimulation on pregnancy rates in women undergoing in vitro fertilization: a study protocol for a randomized controlled trial. *Trials*, 14. Retrieved May 27, 2017, from http://www.trialsjournal.com/content/15/1/162

| **Questions** | **Description** | **Answer to Question** |
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| Were the training and clinical experience of the acupuncturist(s) stated? | "In total, two acupuncturists from each hospital with a minimum of two years of clinical experience will participate in this process." | Yes |
| Were inclusion and exclusion criteria for patient selection presented? | "The inclusion criteria are the following: (1) infertile women <40 years of age undergoing a fresh IVF or intracytoplasmic sperm injection (ICSI) cycle; (2) who have a potentially lower success rate, which is defined as two or more previous unsuccessful ETs (fresh or frozen); (3) who are willing to sign an informed consent form indicating that they are aware of the investigational nature of this study, which is in keeping with the institutional policies; and (4) who are willing to return to the study site for visits.<br>…The exclusion criteria are the following: (1) have major medical illnesses (such as stage III heart disease, severe hypertension, uncontrolled diabetes mellitus, positive HIV status, severe bleeding dyscrasias, etc.) possibly precluding IVF or pregnancy; (2) have FSH levels greater than 20IU/L; (3) have received donor eggs; (4) have cutaneous lesions within the acupoint area; and (5) had previously participated in this study or previously undergone acupuncture (in whatever modality) as infertility treatment." | Yes |

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| Were patients assigned to the treatment group and the control or comparison group by a process described as randomized? | "Included patients will be randomly divided into three groups: the TEAS group (conventional IVF + TEAS), the EA group (conventional IVF + EA), and the control group (only conventional IVF).<br>Fundamental characteristics of randomization include the inability of researchers to predict a patient's assignment and no assignment changes after randomization. The randomization sequence will be generated by a computerized random number generator using the simple-randomization method." | Yes |
| Was demographic and medical history information presented for the patients assigned to the treatment and control/comparison groups? | "Women presenting to the reproductive medicine center of the involved hospitals will be screened for fitness to undergo IVF.<br><br>…Baseline characteristics such as age, infertility type and duration, IVF indication and history, history of smoking or drinking, history of exposure to radiotherapy or chemotherapy, history of pelvic inflammatory disease (PID) or endometriosis, and history of previous pelvic surgeries will be noted." | Yes |
| Were rationales presented for the choice of Acu-points and/or herbs and treatment parameters? | "TCM diagnosis in the great majority of infertile patients is kidney and spleen deficiency, liver qi stagnation, dampness, or blood stasis, or multiple diagnoses. Therefore, acupoints for the TEAS and EA groups are chosen according to the TCM dialectical treatment principle and our former experimental results.<br>…ST36 is an important health care acupoint of the stomach meridian, which can enhance spleen and stomach function and help generate qi and blood. SP6 is the confluent acupoint of food three (kidney, spleen and liver) *yin* meridians, which can supplement the three *yins* and can regulate *qi* and blood. LR3 is the liver meridian *yuan*-source acupoint, which can assist SP6 to sooth the liver and regular *qi* and blood. Bilateral Taixi (KI3) will be added for patients with kidney deficiency, Hegu (LI4) will be added to assist Taichong (LR3) for patients with liver qi stagnation, and Fenglong (ST40) is for patients who have too | Yes |

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| | much dampness in the body. …The combination of ST36, SP6, and LR3 can guarantee basic regulation of *qi* and blood throughout the body." | |
| Were the acupuncture and control/comparison treatments described in sufficient detail that you could repeat them? | "For the EA group, sterile, disposable needles made in Shanghai (China) will be used to a depth of 5 to 20 mm in the selected acupoints after disinfection. The needles will be 25 to 50 mm in length and 0.3 mm in diameter. The *qi* sensation will be achieved by lifting and thrusting movements combined with needle twirling and rotation. Two homolateral acupuncture needles will be connected to form a circuit containing a HANS – 100 B stimulating (Nanjing Jisheng Company, China) for 30 min.<br>…TEAS or EA treatments will start from day 3 of menstruation in the ovarian stimulation cycle once every two or three days, 30 min each for more than two weeks until the day of ET." | Yes |
| Were the clinical endpoints or outcome measures described in sufficient detail that you could use them to repeat the study? | "The primary outcome measure is clinical pregnancy (confirmed by ultrasound scan 5 to 6 weeks after ET demonstrating at least one gestational sac with fetal heart activity.) Secondary outcome measures are live birth (defined as the delivery of one or more living infants, >20weeks gestation or 400 g or more birth weight), number of oocytes retrieval (OCR) and the total gonadotropin dose used in the ovarian stimulation cycle." | Yes |
| Was the assessor of treatment effectiveness described as blinded? | "The assessor will assess the treatment outcome. The assessor will not be the acupuncture practitioner and will be blinded to the allocation results until the end of the study." | Yes |
| Were patients asked to validate the placebo/sham control treatment? | "Included patients will be randomly divided into three groups: the TEAS group (conventional IVF + TEAS), the EA group (conventional IVF + EA), and the control group (only conventional IVF)." | No |

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| Was follow-up data presented? | “This trial is currently preparing to recruit participants. The enrollment will begin on 1 May 2014 and is expected to be completed before 1 May 2016.” | No |
| Was the Acupuncture used in addition to other type of therapy? | “Transcutaneous electrical acupoint stimulation (TEAS) is a combination of transcutaneous electrical stimulation from the West and acupoints from traditional Chinese medicine…but there were no comparisons between TEAS and electro-acupuncture (EA).” | Yes |
| Do I agree with the study outcomes? | “This trial is currently preparing to recruit participants. The enrollment will begin on 1 May 2014 and is expected to be completed before 1 May 2016.” | Not applicable |

Checklist of STRICTA items for the above (Study Article # 5).

| **Intervention** | **Description of Item** | **Answer** |
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| 1) Acupuncture rationale | 1a) Style of acupuncture<br>1b) Rationale for treatment (e.g. syndrome patterns, segmental levels, trigger points)<br>1c) Literature sources to justify rationale | Yes |
| 2) Needling details | 2a) Points used (uni/bilateral)<br>2b) Numbers of needles inserted<br>2c) Depths of insertion (e.g. *cun* or tissue level)<br>2d) Responses elicited (e.g. *de qi* or twitch response)<br>2e) Needle stimulation (e.g. manual or electrical)<br>2f) Needle retention time<br>2g) Needle type (gauge, length, and manufacturer) | Yes |
| 3) Treatment regimen | 3a) Number of treatment sessions<br>3b) Frequency of treatment | Yes |
| 4) Co-interventions | 4a) Other interventions (e.g. moxibustion, cupping, herbs, exercises, life-style advice) | Yes |

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| 5) Practitioner background | 5a) Duration of relevant training<br>5b) Length of clinical experience<br>5c) Expertise in specific condition | Yes |
| 6) Control intervention(s) | 6a) Intended effect of control intervention and its appropriateness to research question and, if appropriate, blinding of participants (e.g. active comparison, minimally active penetrating or non-penetrating sham, inert)<br>6b) Explanations given to patients of treatment and control interventions<br>6c) Details of control intervention (precise description, as for Item 2 above, and other items if different)<br>6d) Sources that justify choice of control | Yes |

**Conclusion of the above study article # 5:**

The latest meta-analysis demonstrated that acupuncture improves pregnancy rates among women undergoing *in vitro* fertilization-embryo transfer, and surface acupoint stimulation, such as transcutaneous electrical acupoint stimulation (TEAS), may have the same or better potential. The primary purpose of this study is to explore whether there are any differences between electroacupuncture and transcutaneous electrical acupoint stimulation in increasing pregnancy rates in women undergoing IVF compared with conventional IVF. To explore the effect of TEAs on the clinical pregnancy rate and live birth rate compared with real acupuncture and controls in women undergoing IVF, a multicenter, randomized controlled trial will be conducted. The subjects will be randomly assigned to the TEAS group, the electro-acupuncture group, or the control group. If successful, this study will provide significant evidence for using a new method in IVF.