Title: Measuring the Effectiveness of Chinese Herbal Medicines in Improving Female Fertility

Author: Trevor A. Wing

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<u>Abstract</u>

Aim: To determine the relationship between female fertility indicators and the administration of Chinese Herbal Medicine (CHM).

Design: A prospective cohort study, using primary clinical study methodology to measure accepted biomedical factors that effect female fertility. It has been established by numerous previous workers that uterine artery heamodynamics, follicle number and size at ovulation, endometrial thickness and, corpus luteum vascularity and serum progesterone levels correlate with pregnancy rates. This previous work is used to provide the metrics to determine if Chinese Herbal Medicine (CHM) can improve these parameters and also pregnancy outcome

Setting: A private London natural female heath practice specialising in treating infertility with Traditional Chinese Medicine (TCM). The study period was between November 2003 and December 2004

Patient(s): Fifty primary or secondary infertile women between 20 and 50 years of age with no diagnosed pathology undergoing TCM infertility treatment who have previously undergone assisted reproductive treatment or who wish to pursue an entirely natural approach to infertility treatment.

Interventions: One monitored (non-treatment) menstrual cycle using ultrasound and serum hormone levels to measure pre-treatment fertility indicators. Specifically, the indicators measured before and after treatment were, serum follicle stimulating hormone (FSH) and endometrial thickness at menstrual cycle day 1, uterine artery heamodynamics, follicle number and size at 2 days pre ovulation, endometrial thickness, serum progesterone level and corpus luteum vascularity at 7 days post ovulation. The treatment given consisted of oral Chinese herbal medicine formulas (CHM) in capsule form administered for 1 menstrual cycle (treatment cycle). Followed by measuring changes in fertility indicators during the second treatment menstrual cycle (i.e. a paired t test).

Results: The results indicated that there were significant differences between the two time points for the majority of the measures examined. For the pre-ovulation measures, the values were found to be significantly higher post-treatment for ovarian follicle numbers and Graafian follicle size which were, on average, 2.8 units higher than those observed pre treatment. Conversely, the values for the cycle day 1 endometrial thickness were significantly lower post treatment than pre treatment. There was a significant difference between pre and post treatment values for all the post-ovulation measures examined. There was no strong evidence of a significant difference between age groups in terms of the difference in response between pre and post treatment. However, the differences were higher for younger patients for the Graafian follicle size and progesterone levels, although these results were not quite statistically significant. The number of pregnancies achieved in the sample group of 50 patients at the submission date (31st May 2005) of this dissertation was 21 pregnancies, 9 live births and 4 miscarriages.

Conclusions: The study utilised well accepted statistical methods of evaluation and the physiological factors measured before and after treatment were also well accepted biomedical measures of female fertility. The study should therefore be of interest to both the TCM and biomedical communities alike concerned with female infertility. The outcome demonstrates that there is merit in terms of higher success rates, reduced patient side effects and reduction in the category of patients traditionally labelled as unexplained infertility.