

Info Sheet: Acupuncture with Clomid and Intrauterine Insemination (IUI)

TITLE: Acupuncture with Clomid and Intrauterine Insemination

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SUMMARY

- For any woman over the age of 18 that is undergoing clomid and intrauterine insemination for unexplained infertility.
- This research study is being done to determine if acupuncture treatments done during the follicular phase of a treatment cycle increases/improves the pregnancy rate.
- This research study has two parts. During the first phase patients with unexplained infertility be divided into two groups – one group will receive acupuncture during their medical treatment and one group will not. This phase will last for one month. The second phase is for women who did not become pregnant during the first phase. They may then self select to be in either the acupuncture or control group. The first phase is a randomized trial and the second phase is a cohort study.
- Four acupuncture treatment sessions for 30 minutes each will be performed.
- Possible benefits are unknown.

PURPOSE OF THE STUDY

This is a study to determine if acupuncture performed in conjunction with the medical treatment of clomid and intrauterine insemination leads to improved pregnancy rates.

Many patients undergoing infertility treatment search for other modalities, such as acupuncture, in hopes of increasing their chances of success. Studies have been conducted in China examining the effects of acupuncture on ovulation induction both with and without clomiphene^{1,2}. The results appear very promising, with a substantial increase in pregnancy rates in those women receiving acupuncture. However, there are several methodological flaws in these studies and none of them examined acupuncture with clomid and IUI for unexplained infertility. Thus, it is uncertain if acupuncture was solely responsible for the increase in pregnancy rates found in these studies.

We feel it is important to know if acupuncture with clomid and IUI will improve the pregnancy rates in women with unexplained infertility. If it does improve pregnancy rates, we would like to offer it to all of our patients. If, however, acupuncture is of no added benefit, knowing this will spare patients the extensive time and financial commitment required by acupuncture treatment. To answer this question, we are conducting a two phase study to determine if acupuncture treatment in the first half of the menstrual cycle improves pregnancy rates. In the first part of the study, which lasts one month, patients will be randomly assigned to receive acupuncture with clomid and IUI or clomid and IUI alone. In the second phase, which lasts up to three months, patients who have not become pregnant can choose which group they would like to participate in. They can select to be in the acupuncture group or in the clomid/IUI only group.

PROCEDURES

If you agree to participate in this study, the following will happen:

1. You will agree not to have acupuncture performed at an outside clinic for the duration of the study.
2. You will undergo clomid and IUI as directed by your physician after consultation with you and your partner (if applicable). Participation in this study will not alter the medical treatment of your clomid/IUI cycle.
3. During the first phase of the study you will be randomized to one of two groups. This means that you will have a 50% chance of being placed in any one of the two groups. You will not be able to choose to which group you will be assigned. Nor will your physician be able to choose to which group you are assigned, so bias in the study is reduced. One group will have clomiphene and IUI alone, without any form of acupuncture. A second group will have four acupuncture treatments during the first half of the menstrual cycle. Needles will be placed in accordance with traditional Chinese Medicine (TCM) principles. Since there is a 50% chance that you will be placed in the clomiphene/IUI only group where you will receive no acupuncture, you will not agree to participate in this study if you are certain that you want to have traditional acupuncture treatment done for the first clomid/IUI cycle. If you do not become pregnant during the first phase of the trial, during the second phase of the study you may select to be in either the clomid/IUI group or the acupuncture plus clomid/IUI group.
4. Patients in the acupuncture group will have four acupuncture treatments between days 3-14 of their menstrual cycle. Each treatment will last approximately 30 minutes.
5. The investigators will collect the following information about you from the chart: age, ethnicity, diagnosis of infertility, history of any previous pregnancies, history of any previous fertility treatment, FSH level, estradiol levels, weight, height, endometrial height, number of follicles produced, size of follicles produced and pregnancy outcome. Information, like your name and date of birth, which can directly link you to these data will be removed by the researchers before analyzing the data.

RISKS AND DISCOMFORTS

The risks of participating in the study include:

1. The complications of acupuncture. While acupuncture is generally safe, both minor and serious adverse events have been associated with its use. The most common side effect reported was a feeling of relaxation (86% of patients) while the most common adverse event was needle pain (1-45%), followed by tiredness (2-41%) and then bleeding (3-38%). Serious events such as pneumothorax, cardiac tamponade, overwhelming infection, or death have been reported but are extremely rare³.

Additionally, deleterious effects of acupuncture on fertility may occur; as the effects of acupuncture on clomid/IUI treatment have not been formally tested in this country, there is the possibility that acupuncture may decrease clomid/IUI success.

2. The risk of randomization: During the first phase of the trial, each patient will be assigned to a study group by chance. The treatment a patient receives (either clomid/IUI or acupuncture plus clomid/IUI) may be less effective or have more side effects than the other study group.
3. Your condition may not get better or may get worse during this study.

BENEFITS

There are no known benefits to you personally in participating in this research study. The benefit is only to other women with unexplained infertility who will be undergoing clomid/IUI treatment in the future. If acupuncture does improve the success rates of this therapy, the standard of care for infertility patients will change. If no difference in success rates is found, future patients will benefit from the knowledge that the significant time and financial commitment of acupuncture will not improve their chances of a more successful outcome.

COSTS

There will be no charge for the acupuncture procedure.

PAYMENT FOR PARTICIPATION

You will not be reimbursed for your time in participating in this study. Nor will you receive payment for participating in the study.

ALTERNATIVE TREATMENT

The alternative is to choose not to participate in the study. If you choose not to participate in this study, you will receive the same treatment as all patients undergoing embryo transfer in our facility. Specifically, you will be released from the clinic immediately after the procedure has been completed.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Taking part in this study is voluntary. You may decide not to take part or you may leave the study at any time. Your decision will not cause any penalty or loss of benefits to which you are entitled. If you decide to leave the study, please notify the study coordinator.

The study doctor or the sponsor may stop your participation in this study at any time without your consent for any of the following reasons:

- it is in your best interest
- you do not later consent to any future changes that may be made in the study plan
- or any other reason

REFERENCES

1. Peng, Y., Hou, L.H., Wu, X.K. Advances of modern studies of acupuncture and moxabustion treatment of ovulation disorders. *Chinese Acupuncture and Moxabustion*. 10, 756-9 (2006).
2. Song, F.J., Zheng, S.L., Ma, D.Z. Clinical observations on acupuncture for treatment of infertility of ovulatory disturbance. *Chinese Acupuncture and Moxabustion* 28, 22-23 (2008).
3. Ernst, E. & White, A. R. Prospective studies of the safety of acupuncture: a systematic review. *American Journal of Medicine* 110, 481-5 (2001).