

Info Sheet: Acupuncture and Treatment with In Vitro Fertilization

TITLE: Acupuncture and Treatment with In Vitro Fertilization

SPONSOR: Fertility Physicians of Northern California

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SITE(S): Fertility Physicians of Northern California, San Jose and Palo Alto Offices

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SUMMARY

- For any woman over the age of 21 that is undergoing IVF.
- This research study is being done to determine if having a 30 minute acupuncture treatment done immediately before and immediately after an embryo transfer increases/improves the pregnancy rate.
- During the research, patients will be divided into two groups – one group will receive acupuncture before and after embryo transfer, the other group will receive bedrest before and after the embryo transfer.
- Procedure will be 30 minutes of acupuncture before and after the embryo transfer; or bedrest.
- Possible benefits are unknown.

PURPOSE OF THE STUDY

This is a study to determine if acupuncture performed immediately before and immediately following embryo transfer (ET) alters the success rates of in vitro fertilization (IVF).

Many patients undergoing IVF therapy search for other modalities, such as acupuncture, in hopes of increasing their chances of success. While proponents of this therapy often cite a substantial increase in the pregnancy rate with its use¹, there is only one study which has directly compared the combination of treatment to IVF alone². In this study, the patients who received acupuncture had pregnancy rates comparable to similar women in our clinic who do not use acupuncture, while those patients who did not receive acupuncture had pregnancy rates that were lower than would normally be expected. Because of this, the difference in pregnancy rates may not have been due to an improvement with acupuncture but rather a difference in the women who were assigned to the group without acupuncture.

We feel it is important to know if acupuncture will improve the success rates of IVF. 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 randomized controlled trial to determine if acupuncture before and after embryo transfer improves pregnancy rates. Patients will be randomly assigned to receive traditional acupuncture or bedrest and their outcomes will be monitored.

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 before and after embryo transfer. If you choose to have this performed at an outside clinic, you will notify the study coordinator. If you undergo other treatment protocols of acupuncture at an outside facility, you may still participate in this study as long as you notify the study coordinator of this activity and the frequency at which you are having acupuncture performed.

2. You will undergo in vitro fertilization 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 IVF cycle.
3. 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 bedrest alone, without any form of acupuncture. A second group will have acupuncture needles placed in accordance with traditional Chinese Medicine (TCM) principles. Since there is a 50% chance that you will be placed in the bedrest 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 your embryo transfer.
4. If you are randomized to the bedrest group, you will lay in a comfortable position for thirty minutes before and for thirty minutes after the embryo transfer. You will not have traditional acupuncture performed before or after the embryo transfer and you agree not to seek this treatment at an outside facility.
5. If you are randomized to the acupuncture group, you will agree to complete a thirty minute session of traditional acupuncture both immediately before and immediately after the embryo transfer.
6. 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 assisted reproductive technology cycles, FSH level, estradiol levels, weight, height, stimulation protocol, the number and grade of embryos transferred, the number of embryos which implanted, and the outcome of any pregnancy. 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 IVF treatment have not been formally tested in this country, there is the possibility that acupuncture may decrease IVF success.

2. The risk of randomization: Each patient will be assigned to a study group by chance. The treatment a patient receives (either bedrest or acupuncture) 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 infertility who will be undergoing IVF treatment in the future. If acupuncture does improve the success rates of IVF 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. Liang, L. Acupuncture and IVF (Blue Poppy Press, Boulder, CO, 2003).
2. Paulus, W. E., Zhang, M., Strehler, E., El-Danasouri, I. & Sterzik, K. Influence of acupuncture on the pregnancy rate in patients who undergo assisted reproduction therapy. *Fertility & Sterility*. 77, 721-4 (2002).
3. Ernst, E. & White, A. R. Prospective studies of the safety of acupuncture: a systematic review. *American Journal of Medicine* 110, 481-5 (2001).