The Effectiveness of Acupuncture on Headaches in Women Undergoing IVF Egg Stimulation: A Pilot Pre-Post Observational Study

NCT: ID not assigned yet

Date of Document: January 12, 2023

Informed Consent Form: Study Consent Form

YO SAN UNIVERSITY
CONSENT TO ACT AS A HUMAN RESEARCH SUBJECT

Efficacy of Acupuncture on Headaches in Women undergoing IVF Egg Stimulation

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STUDY LOCATION(S):
Southern California Reproductive Center Beverly Hills
450 N Roxbury Drive #500
Beverly Hills, CA 90210
310 277 2393

STUDY SPONSOR(S): none

SUMMARY OF KEY INFORMATION:

The information provided in this box includes a brief yet complete summary of key information about the research, presented first as required by the federal regulations. Some sections that require additional information may be repeated later in this document.

Participation is Voluntary
You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed above will be available to answer your questions.

Study Purpose
The purpose of this study is to identify whether acupuncture treatment will have an effect on headaches caused by in vitro fertilization drugs and hormones during an egg stimulation cycle.

Study Procedures
You will be asked to complete consent paperwork, a survey before acupuncture treatment, and a survey after acupuncture treatment.

Expected Duration
Total time commitment of filling out surveys is estimated at approximately 10-15 minutes. The acupuncture treatment will require the usual time commitment of 45 minutes. Total time commitment of participating in the survey including the acupuncture treatment should be about an hour. Results of the study will be available in August 2023.

Risks of Participation
The general risks of acupuncture needling include bruising, numbness or tingling at the needling site, fatigue or dizziness. Unusual risks of acupuncture include nerve damage and organ puncture, including lung puncture (pneumothorax). Infection is another possible risk, although the clinic uses sterile disposable needles and maintains a clean and safe environment. Also, should there be a breach of confidentiality of the study data, there is a slight risk that written copies or transcripts of your surveys might be seen by individuals other than the primary researcher, co-researcher or secondary site.

Benefits to Participants
The possible benefits you may experience from your participation in this study include relief from the acupuncture treatment. Additionally, a sense of satisfaction from sharing your experience with a broader audience, as well as a sense of satisfaction and the opportunity to gain knowledge from reviewing the final research if you choose to do so.

Benefits to Others or Society
Both TCM and Western fertility healthcare providers may benefit from increased knowledge and understanding of the ways TCM care can benefit patients who experience headaches as side effects of hormonal stimulation and serve an adjunctive role to standard Western fertility care. Fertility patients, their families, and their communities may also benefit from this increased understanding.

Alternative Procedures or Treatments
There are no alternative procedures available. The only alternative is not to participate in this study. You may still review the final research if it is of interest to you.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?
You must meet the following requirements to be in the study: female with headaches, undergoing hormonal stimulation for a retrieval at SCRC in Beverly Hills. Female participants who have histories of headaches, hypertension, hypotension, or caffeine intake will be noted in the study.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY AND HOW LONG WILL THEY TAKE?
1. Primary Researcher will begin recruitment in February/March 2023 and administer surveys until April/May 2023 to meet required population minimum. Data analysis will occur from May-July 2023. Final capstone will be presented in August 2023.
2. Participation in the study will include completing two surveys: one pre acupuncture appointment and one post acupuncture appointment.

WHAT ARE THE POSSIBLE DISCOMFORTS OR RISKS RELATED TO THE STUDY?
The possible discomforts or risks related to the study are listed above under *Risks of Participation.* Possible risks will be due to the actual acupuncture treatment or in the event of a breach of secure information.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?
You will not be compensated for your participation in this study.

Reimbursement
You will not be reimbursed for any fees, including the acupuncturist fee or any fees related to your procedure at SCRC.

Costs
There is no cost to you for participation in this study beyond that of your time.

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?
You are free to withdraw from this study at any time. **If you decide to withdraw from this study you should notify the research team immediately**. The research team may also end your participation in this study if attempts to collect data become unnecessarily cumbersome for either party or if your experience is not relevant.

If you elect to withdraw or are withdrawn from this research study, the researchers will discuss with you what they intend to do with your study data. Researchers may choose to analyze the study data already collected or they may choose to exclude your data from the analysis of study data and destroy it, as per your request.

HOW WILL MY PERSONAL INFORMATION BE KEPT?
Subject Identifiable Data
Identifiable information collected about you will be kept with the research data. Data includes only information that you choose to share on the completed surveys as well as basic demographic information including age and gender.

Data Storage & Retention
Research data will be stored physically in a locked drawer at a secure location. Data may also be stored electronically on a password-protected laptop computer. The surveys will be retained with the other research data and will be destroyed within 7 years.

WHO WILL HAVE ACCESS TO MY STUDY DATA?
The primary researcher will have total access, and the Capstone Advisor, Secondary Site, and Program Dean may also have limited access to your study records to advise the primary researcher in data analysis.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

Future Research Use
Researchers will use your information to conduct this study. Once the study is done using your information, we may share it with other researchers so they can use it for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?
No one on the study team has a disclosable financial interest related to this research project.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?
If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?
You should not sign this consent form until all your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with Yo San University.

_____ Yes, I agree to allow the research team to use my completed surveys for this study
_____ No, I do not agree to allow the research team to use my completed surveys for this study

*Consent to use your completed surveys is a minimum requirement for participation in the study to allow for accurate review of information and subsequent data analysis.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

I agree to participate in the study.

_____ _____
Subject Signature **Date**

_____
Printed Name of Subject

_____ _____
Signature of Person Obtaining Informed Consent **Date**
(For research that is greater than minimal risk, this individual must be listed on Page 1 of this consent)

_____
Printed Name of Person Obtaining Informed Consent