

Research Study Informed Consent

Protocol #19785 – Use of Low-level Laser Therapy to Stimulate Acupuncture Points for the Treatment of Tobacco Addiction

Study Participant Name: _____

Clinical Investigator Name: _____

Phone Number: _____

Research Sponsor: **Laser Thera, LLC**
5300 N Meridian Ste 1
Oklahoma City, OK 73119
888-502-9955

Introduction

This study involves research to determine the effects of using low level laser therapy to stimulate acupuncture points to assist individuals in their efforts to stop smoking. The total anticipated duration of the study is three months, including follow up by the Clinical Investigator. The procedure uses light concentrated by the laser directed at various acupuncture points on the body. The first procedure will last approximately 30 minutes and subsequent treatments last approximately 20 minutes. The number of visits required is between one and six. The procedure and use of the laser device are considered experimental.

Potential Risks or Discomforts

There are no known side effects from the use of laser. On rare occasions, temporary redness, a tingling sensation or mild pain may occur during or after treatment. These effects normally disappear quickly, usually 1 to 3 hours after treatment. Since this procedure and the use of this device are experimental, there may be the possibility for unknown reactions. You will be required to wear protective eyewear throughout the treatment to prevent any accidental damage to the eye from direct exposure to the laser light.

Potential Benefits

The use of low level laser therapy on acupuncture points for this study may assist you in your efforts to stop smoking. The laser treatment may lessen the craving for cigarettes, which could assist you in overcoming the physical need to smoke.

Alternative Procedures or Treatments

You should be aware that participation in the research study is voluntary and that there are other options to assist you in your desire to stop smoking. Some options include prescription drugs, over-the-counter drugs, and acupuncture therapy.

Confidentiality

The confidentiality of your records is very important to us. Your clinical investigator has agreed to comply with HIPAA requirements for the protection of the confidentiality of your records. Your clinical investigator will use your records to compile the required documentation for the Research Sponsor and the IRB for submission to the FDA. The FDA may inspect study records (including individual medical records) without clearance or permission. If any other entity requests access to the records, you will be informed.

Injuries Resulting from the Study

If you feel that you have been injured as a result of the study, have not been treated fairly, or have questions about the study, please contact Shelly Henry of Laser Thera, LLC, the research sponsor, at (888)502-9955. No funds have been set aside for compensation in case of injury.

Voluntary Participation

Participation in this research study is voluntary. Refusal to participate at any time during the study will involve no penalty or loss of benefits to which you are otherwise entitled.

Cost of Study

The costs related to the research will not be covered by this study. You will be responsible for any costs which include diagnostic procedures and office visits. The cost of treatment is \$399.00. For exact costs in your area, contact your Clinical Investigator.

Statement of Voluntary Participation

The study for the use of low-level laser therapy to stimulate acupuncture points for the treatment of smoking addiction as well as the risks, benefits, alternative procedures and purpose of the study have been explained to me in a manner in which I understand. I have been given the opportunity to ask questions and my questions were answered to my satisfaction. I may contact _____ at _____ if I have any additional questions regarding this study.

I understand that my participation in this research study is voluntary. I know that I may quit this study at any time and that I may be withdrawn from the study if I fail to follow the instructions provided by the Clinical Investigator. I also understand that the Clinical Investigator in charge of the study may decide at any time that I should no longer participate in this study.

By signing this form, I have not waived any of my legal rights.

I have read and understand the information contained in the Laser Thera, LLC informed consent document. I agree to participate in this study. I have been given a copy of this signed and dated document for my own records.

Study Participant (Signature)

Date

Study Participant (Print Name)

Intake Coordinator (Signature)

Date

Intake Coordinator (Print Name)

Witness (Signature)

Date

Clinical Investigator (Signature)

Date