Informed Consent

TITLE: invisaRED® IR REHAB Clinical Trial Protocol

PROTOCOL NO.: None
WCG IRB Protocol #20241885

SPONSOR: Stephen Reardon

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(678) 232-8861
(678) 836-6081
(678) 767-2423 (24 hours)

NAME OF ORGANIZATION: IR Technology, LLC

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have questions, concerns, or complaints, or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

How long will I be in this research?

We expect that your taking part in this research will last three weeks.

Why is this research being done?

The purpose of this research is to test the effectiveness of invisa-RED™ IR REHAB as an investigational device that will administer low-level laser therapy for temporary relief of nociceptive (pain caused by damage to body tissue) musculoskeletal pain.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, the general procedures include receiving two 15-minute treatments weekly for three weeks. You will be randomly assigned to receive either low-level laser therapy or a sham therapy. You will not know what therapy type you are assigned to receive. For each of the 15-minute therapy sessions, either low-level laser therapy paddles or sham paddles will be placed on exposed areas of your body to be treated for pain while you are lying on a treatment table. In the sham therapy, the doctor or research staff go through the motions of the therapy session, but no actual low-level laser therapy will be given. You will complete a pain level questionnaire before and after treatments.

Could being in this research hurt me?

The most important risks or discomforts that you may expect from taking part in this research include light laser therapy which could cause eye injuries, minor burns or blisters, and you may feel sluggish or have flu like symptoms.

Will being in this research benefit me?

The most important benefits that you may expect from taking part in this research include the potential to reduce your level of pain in the areas of your body that are treated. However, there may not be any benefit for you, but your participation may benefit others in the future.

What other choices do I have besides taking part in this research?

Instead of being in this research, your choices may include continuing any of your current therapies and medications.

What else should I know about this research?

Other information that may be important for you to consider so you can decide whether to take part in this research is that you should be adequately hydrated during the entire three-week study. Do not apply any gels, lotions, or essential oil on the body areas that will be treated.

Your information or biospecimens collected as part of the research, even if identifiers are removed, will not be used, or distributed for future research studies.

DETAILED RESEARCH INFORMATION

Informed Consent Form for Prospective Trial Participants

This Informed Consent Form is for men and women who are under consideration to participate in a non-invasive pain relief therapy trial using the invisa-RED™ IR REHAB device at IR Medical Centers.

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the research with you)**
- **Certificate of Consent (for signatures if you agree to take part)**

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

I am Dr. Ajibola Babatunde of IR Medical Centers. We are doing research on pain relief using Low Light Laser Therapy (LLLT). I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask me or the study staff.

Purpose of the research

This study will test the effectiveness of invisa-RED™ IR REHAB as a new investigational device that will administer Low-level laser therapy for the temporary relief of nociceptive musculoskeletal pain.

Type of Research Intervention

This research will use non-invasive LLLT compared to a sham device to study adjunctive (additional) temporary relief of nociceptive musculoskeletal pain.

Participant selection

We are inviting all adults who meet the criteria to participate in the research. We anticipate 30 participants will participate in this research. Participants will be randomly assigned, like flipping a coin, to either receive the low-level laser therapy with the invisa-RED™ IR REHAB device or receive treatment with a sham device. You have a 50% chance of being assigned to either treatment group.

Participant Exclusion Criteria

Please answer the following questions.

Answering any question "yes" will not qualify you for the invisa-RED Elite clinical trial.

	YES	NO
Are you under eighteen (18) years of age?	☐	☐
Are you pregnant, trying to get pregnant or nursing?	☐	☐
Do you have any of these conditions: hypertension, light sensitive epilepsy, cancer, heart disease, infectious skin disease, or severe varicose veins?	☐	☐
Are you currently suffering from an infectious or acute disease (such as cough, stomach ache, diarrhea, vomiting, nausea, sore throat, not feeling well) or within the last week had a fever?	☐	☐
Do you have hemorrhagic disease, vascular ruptures, skin inflammation, or any disease of the skin?	☐	☐
Do you have any immune system dysfunction such as Leukemia, Hemophilia, etc.?	☐	☐
Do you have any light sensitivity?	☐	☐
Do you have a history of melanoma, raised moles, suspicious lesions, keloid scar formation, or healing problems?	☐	☐
Do you have any active infections, open lesions, hives, herpetic lesions, cold sores, or tattoos and permanent make-up in the area of treatment?	☐	☐
Have you used isotretinoin (commonly known as Accutane), tetracycline, doxycycline, St. John's Wort, or any photo sensitizing drugs in the last year?	☐	☐

Do you suffer from any autoimmune disease such as Lupus, Scleroderma, or Vitiligo? ☐ ☐

Do you have a pacemaker or other electro-stimulation devices surgically implanted? ☐ ☐

Are you an insulin dependent individual? ☐ ☐

Have you had previous laser treatment and if so, did you experience any problems? ☐ ☐

Do you have a history of lentigines (an autoimmune vascular disease that causes color changes in the legs or arms due to obstruction or stenosis of blood vessels)? ☐ ☐

Do you have a history of erythema (a type of rash caused by persistent or repeated exposure to intense heat or infrared radiation)? ☐ ☐

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you may receive at this clinic will continue and nothing will change. You may change your mind later and stop participating even if you agreed earlier – this will not result in any penalty or loss of benefit to which you are otherwise entitled.

Procedures and Protocol

All therapy sessions will be conducted at the IR Medical Center in Woodstock, GA.

All participants will receive 6 treatments over a period of 3 weeks.

- You will receive two (2) treatments weekly, each lasting 15 minutes, at the IR Medical Center in Woodstock, GA.
- You must wait at least 48 hours between treatments
- All participants should be adequately hydrated during the entire three (3) week trial in order to obtain optimum results and minimize any sluggish or flu like symptoms due to release of stored toxins by the body.
- A suggested hydration schedule for each treatment day is: 16 oz of water 2 hours before treatment, 16 oz of water immediately following treatment, and 16 oz of water 2 hours after treatment.
- Please no food, alcohol, caffeine or nicotine 2 hours before treatment
- Do not apply any gels, lotions, or essential oil on body areas that will be treated.
- Shower before treatments and make sure no cream or perfumed products have been applied to the skin for at least 24 hours before.

- Do not look into the direct or reflected beam during treatment. Operator and participant will wear protective glasses or goggles at all times during treatment. These will be provided to you.
- Data will be recorded before, during and after the study. The data collected will include:
    - Medical health history
    - Demographic information
    - Body height/weight
    - Pain levels before and after treatments using a Visual Analog Scale or VAS.
- The clinic staff will be looking after you and the other participants very carefully during the study. If there is anything you are concerned about or that is bothering you about the research please speak to me or one of the other researchers.

Description of the Process

For the each of the 15 minute therapy sessions Low Level Laser Therapy or LLLT "paddles" or sham paddles will be placed on exposed areas of your body to be treated for pain, while lying on a treatment table.

Duration

The research takes place over 3 consecutive weeks.

Risks

The laser beam could cause eye injuries. Minor burns or blisters may result from laser light energy applied to the skin.

Light laser therapy may result in feeling sluggish or flu like symptoms due to release of stored toxins by the body.

There may be unknown risks that appear during treatment. The healthcare workers will be looking after you and the other participants very carefully during the study. If any concerns noted by our staff arise during the study we will notify you and with your consent make the appropriate adjustments for your well-being.

The IR REHAB device employs Class 3b laser diodes in a system of "paddles" which are placed on the area of your body to be treated. Class 3B lasers are hazardous for eye exposure; therefore during therapy protective eyewear is provided for staff, the individual undergoing treatment, and any others in the room. Eye safety is further enhanced by standard IR REHAB clinical procedures, which are designed to eliminate exposure of the eyes of the participant and proximate individuals to direct laser light. These clinical procedures dictate that the paddles are

to be placed on the area to be treated (secured if required) and then and only then the system is activated and treatment begun.

This helps eliminate the chance of any direct laser light entering the eye.

Class 3B lasers can heat skin and materials but are not considered a burn hazard. However treatment protocol standards allow for power settings be adjusted for you based on skin type; as differing skin tones result in a variable coefficient of absorption of electromagnetic energy. **Be advised the therapy may result in a mild sunburn like effect, blisters, or skin sensitivity, but this is rare**. Additionally, you will be asked to verbally attest to your comfort level at the start of each therapy session. The study team will ask you about any side effects from the last treatment before any subsequent treatment. You should report any side effects you experience during the study to the research team.

The following contraindications and precautions for participants apply:

- If you are pregnant, trying to get pregnant or nursing laser light therapy should be received only after the end of these conditions. There is no evidence of harm to an unborn baby however there have been no safety tests either, so for medical legal reasons we recommend never treating areas directly over a developing child.
- Individuals with hypertension, light sensitive epilepsy, cancer, heart disease, infectious skin disease, and severe varicose veins should not use this device.
- People suffering from infectious and acute disease such as a fever should not use this device.
- People who have hemorrhagic disease, vascular ruptures, skin inflammation, or any disease of the skin should not use this device.
- People who have immune system dysfunction such as Leukemia, Hemophilia, etc., and light sensitive persons should not use this device.
- Use of laser light therapy in the ears, nose, eye, or throat is not recommended.
- Individuals with a history of melanoma, raised moles, suspicious lesions, keloid scar formation, or healing problems should not undergo laser light therapy.
- People who have used isotretinoin (commonly known as Accutane), tetracycline, doxycycline, St. John's Wort, or any photo sensitizing drugs in the last year should not undergo laser light therapy.
- Individuals with active infections, open lesions, hives, herpetic lesions, cold sores, or tattoos and permanent make-up in the area of treatment should not undergo laser light therapy.
- Individuals with autoimmune diseases such as Lupus, Scleroderma, or Vitiligo should not undergo laser light therapy.
- Individuals who have pacemakers or other electro-stimulation devices surgically implanted should not undergo laser light therapy.

- Any insulin dependent individual should consult their physician before undergoing laser light therapy.

New Findings

You will be told about any new information that might change your decision to be in this study.

Benefits

If you participate in this research, you may have the following benefits: You have the potential to reduce your level of pain in the areas of your body treated. However there may not be any benefit for you but your participation is likely to help us find the answer to the research question which may benefit others in the future.

Alternatives

You do not have to take part in this study to control or reduce your level of pain. This device is for adjunctive or “additional” pain relief so you may continue any of your current therapies and medications.

Costs and Reimbursements

There is no cost to you to participate in this study. You will not be paid for being in this study. The results from this study may lead to new commercial products or tests. If this happens you will not receive any compensation.

Confidentiality

It is possible that if others in the community are aware that you are participating in this research, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be securely stored. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except the Investigator Dr. Ajibola Babatunde, the research Sponsor Stephen Reardon, research Administrator Thomas A Namynanik, IR Medical Center clinicians, the FDA, and WCG IRB.

Sharing the Results

Confidential information will not be shared. The results of this study may not be made available to you. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice and all of your rights will still be respected.

Removal from Research

The investigator in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You need a treatment that is not allowed in this research
- You become pregnant
- You are unable to keep your scheduled appointments

Who to Contact

If you have any questions, concerns, or complaints you may ask/report them now or later, even after the study has started. If you wish to ask questions later or if you feel you have been injured by the research, you may contact:

Dr. Ajibola Babatunde
Midnight Rose LLC dba Abbycare
6380 Bells Ferry, Suite 107
Acworth, GA 30102
Phone: (470) 506-0942, (678) 232-8861, (678) 836-6081, or (678) 767-2423 (24 hours)

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.

- You have questions about your rights as a research subject.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Questions

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant

_____

Signature of Participant

_____

Date

_____/_____/_____
Day/month/year

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1. **Participant will undergo six (6) sessions using the IR REHAB device or the sham device as described in the trial protocol.**

2. **For the area of the body that is to undergo therapy the participant will be presented a Visual Analog Scale before each treatment and asked to indicate the previous 24hrs worst level of pain. Five (5) minutes after each of the six (6) therapy sessions the participant will again be asked to indicate the current level of pain using a Visual Analog Scale to determine the efficacy of the treatments with the IR REHAB device for pain relief.**

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent_____

Signature of Researcher /person taking the consent_____

Date

_____/_____/_____
Day/month/year