invisa-RED IR REHAB™ FDA 510 K
Clinical Trial Protocol, Statistical Analysis Plan, Results, and Conclusions

Clinical Trial to Establish the Safety and Efficacy of the IR REHAB Device When Used as an Adjunctive Therapy for Nociceptive Musculoskeletal Pain
FDA Study NCT06393088

December 10, 2024

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invisa-RED IR REHAB Clinical Trial Protocol

Purpose of the Study
The trial is designed to provide data with which to evaluate the efficacy and safety of the invisa-RED® IR REHAB Low-level Laser Therapy (LLLT) device as compared with a sham device when used for the adjunctive treatment of nociceptive musculoskeletal pain . This will be a single blind trial of two groups of equal number; one group will be treated as usual, the other treated using a sham device. At the conclusion of the trial; results from the two groups will be statistically analyzed to determine the efficacy of the IR REHAB machine for the adjunctive treatment of musculoskeletal pain.

Background
"Musculoskeletal pain is a challenging condition for both patients and physicians. Many adults have experienced one or more episodes of musculoskeletal pain at some time of their lives, regardless of age, gender, or economic status. It affects approximately 47% of the general population. Of those, about 39–45% have long- lasting problems that require medical consultation. Inadequately managed musculoskeletal pain can adversely affect quality of life and impose significant socioeconomic problems."[1] The invisaRED® IR REHAB has been developed to deliver adjunctive pain therapy for musculoskeletal pain.

Criteria for Participants
The number of participants is projected to be thirty (30).

There will be an equitable distribution of male and female participants.

Women who are pregnant, trying to get pregnant, or nursing will be excluded from the study, as they should not receive Low-level Laser Therapy (LLLT). There is no evidence of harm to a an unborn baby however there have been no safety tests either, so for medical legal reasons we recommend never treating such individuals.

The participants will be 18 years or older.

The ethnicity of the participants will be equitably distributed.

Inclusion criteria will be individuals that may benefit from an adjunctive therapy for nociceptive musculoskeletal pain.

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[1] El-Tallawy, Salah N et al. "Management of Musculoskeletal Pain: An Update with Emphasis on Chronic Musculoskeletal Pain." *Pain and therapy* vol. 10,1 (2021): 181-209. doi:10.1007/s40122-021-00235-2

Subject Qualification

No candidates of diminished capacity will be considered for inclusion in the trial. Capacity is a functional assessment and a clinical determination about a specific decision that can be made by any clinician familiar with a patient's case. The four key components addressed during the candidates capacity evaluation include: 1) communicating a choice, 2) understanding, 3) appreciation, and 4) rationalization/ reasoning.

No monetary remuneration will be offered participants in the study. At the conclusion of the clinical trial, and upon approval by the FDA, a commensurate number of treatments with the IR REHAB device will be offered to those patients who received treatment using the sham device. This will provide the participants treated with the sham device the opportunity to undergo therapy using an activated IR REHAB device.

All persons interviewed for the trial will be selected using the established invisaRED Technologies IR REHAB guidelines for indications and contraindications. Combining the guidelines for indications and contraindications with the thorough classroom review and "hands on training " for clinicians who will be conducting the trial, the risk is best compared to exposure to sunlight.

Subjects of the study receiving the invisaRED Technologies IR REHAB therapy may receive the following benefits:

- Open up blood vessels to increase circulation and ease swelling
- Help your immune system create more chemicals that heal tissue
- Build more connective tissue in injured area
- Trigger endorphins, natural hormones that ease pain
- Drug free alternative without a chance of addiction
- Noninvasive therapy
- No known side effects

Criteria for Participants:

Participants will be taken from a random population of respondents to email and social media recruitment, in person offers to participate to existing patients, and individuals in the community who have seen signage advertising the trial. The number of participants is projected to be thirty (30). There will be an equitable distribution of male and female participants. The participants will be older than the age of 18 years. Inclusion criteria will be individuals that may benefit from an adjunctive therapy for nociceptive musculoskeletal pain.

Exclusion criteria will include the following:

- For women who 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 against treatment during these times.

- Individuals with uncontrolled 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.

- Person with 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.

- A person with a history of erythema, an acquired, long-lasting reticulocyte red and pigmented rash, caused by persistent or repeated exposure to intense heat or infrared radiation.

- Persons who are susceptible to or have a history of herpes in the treatment area

- Anyone who has experienced problems subsequent to previous laser treatments

- 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

- 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.

- People who have used isotretinoin (commonly known as Accutane), tetracycline, St. John's Wort, or any photo sensitizing drugs in the last year should not undergo laser light therapy.

- Individuals with autoimmune diseases such as Lupus, Scleroderma, or Vitiligo should not undergo laser light therapy.

Exclusion Criteria - continued

- 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.
- All individuals considered “vulnerable” such as children, pregnant women, nursing home residents or other institutionalized persons, students, employees, fetuses, prisoners, and persons with decisional incapacity.

Subject Identification, Recruitment And Consent/Assent

At roadway intersections in close proximity to the Abbycare/IR Medical Centers Clinic located at 1105 Parkside Ln, suite 1300, Woodstock, GA 30189 road side signs will be erected containing the verbiage: “Pain and Injury Study, No Cost, Call 770 988-5594”
This will be done in order to recruit study volunteers from the community.The clinic’s primary care patients will also be provided an opportunity to volunteer for consideration as a trial participant.The primary investigator will conduct all subject interviews and obtain informed consent. A thorough disclosure of all clinical process, contraindications, and any risk will be discussed with candidates for the trial. All candidates will be older than the age of majority in the state of Georgia (18 years old). There shall be no cost incurred by candidates for inclusion in the study or individuals selected to participate in the study.

Methods and Procedures

The trial is designed to prove the efficacy and safety of the invisa-RED Technology IR REHAB device when used as prescribed as an adjunctive therapy for musculoskeletal pain . The trial will compare results between two groups; the first will be treated using the invisa-RED Technology IR REHAB and the second group with a sham (placebo) device.

The trial will be conducted employing a single blind study methodology; participants will not know to which trial group they have been randomly assigned. Participants randomly selected for the control or Sham (placebo) Group will undergo therapy sessions with a disabled IR REHAB device producing no laser energy, however, this sham device will power up the console and fans to appear to be operating normally. If a participant questions the efficacy of the sham device, an assertion may be made that only a near infrared, non-visible frequency of light, is being employed. The control group receiving treatments using the sham device will be scheduled for treatment at times other than participants who will undergo therapy sessions with the fully functioning device in order to ensure the trial blind.

All participants will undergo treatments 2 times weekly for 3 weeks. Treatment will be 15 minutes each session. For each 15 minute session a singular adjustment to the laser’s power output will be made based on the participants standard Fitzpatrick Skin Type. This power adjustment ensures optimal photonic energy absorption, enhanced efficacy, and participant safety. The minimum time between any participants’ scheduled treatments will be 48 hours.

Methods and Procedures - continued
Prior to each therapy session the participant will be asked to record their pain level using a Visual Analog Scale (VAS) and then in the same manner after each treatment using the same Visual Analog Scale (VAS). The results from the two groups will be statistically analyzed to determine the efficacy of the invisa-RED Technology IR REHAB as an adjunctive therapy for nociceptive musculoskeletal pain. Any medical errors will be included in the statistical analysis.

Data Analysis and Data Monitoring
The mean change in each group of participant's pain levels as recorded at the trials beginning and then at the trials conclusion will be statistically evaluated using a two-tailed independent sample T-test with an a priori threshold p value of < (less than) 0.05.

Monitoring Plan
The study is classified as a minimal risk trial of short duration therefore a detailed plan for monitoring the data for participant safety is not required.

Data Storage and Security
All individuals participating in the trial will be assigned a participant number. Subsequently all clinical records and reports will reference only the participant number, ensuring that participants remain anonymous. Because of the low number of trial participants, only paper records will be maintained for all clinical and personal data. Records will be kept in locked storage and physical access will only be on a need to know basis. A participants' personal data correlating the participating individuals name and the trial participants Identifying Number will only be available to the principal investigator, clinical staff, and the trial administrator. All analytics will be performed on securely encrypted devices using only data masked or redacted of any personal information.

Risk/Benefit Assessment
Applying the test for the determination of risk established by the FDA Regulation referred to as the "Common Rule" found in 45 CFR 46, Subpart A the rule states;
"*Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

We have determined that only a minimal risk is presented to participants of the trial

See the detail minimal risk criteria analysis below:

I) The device is NOT intended as an implant that presents a potential for serious risk to the health, safety, or welfare of a subject. The invisa-RED IR REHAB employs no implanted devices as part of any treatment or therapy.

II) The device is NOT purported or represented to be for a use in supporting or sustaining human life that presents a potential for serious risk to the health, safety, or welfare of a subject.

III) The invisa-RED IR REHAB is only to be used as directed as an adjunctive therapy for nociceptive musculoskeletal pain and is not represented or employed as a life sustaining device or therapy.

Risk/Benefit Assessment - cont.

IV) The device is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health that presents a potential for serious risk to the health, safety, or welfare of a subject.

V) The invisa-RED Technology IR REHAB is to be used only as directed as an adjunctive therapy for nociceptive musculoskeletal pain.

VI) The device does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject.

VII) The invisa-RED IR REHAB is classified as an FDA Class II device and has passed all FDA electromagnetic compatibility (EMC) standards.

VIII) The invisa-RED IR REHAB device employs Class 3b laser diodes in a system of "paddles" each containing multiple diodes. Class 3B lasers are hazardous for eye exposure; therefore during therapy protective eyewear is prescribed for staff, the individual undergoing treatment, and any others in the room. Eye safety is further enhanced by standardized invisa-RED Technology IR REHAB clinical procedures, which are designed to eliminate exposure of the eyes of the patient and any proximate individuals to direct laser light. IR REHAB clinical procedures which are found in the manual and are stressed as mandatory during user training dictate that the paddles are to be 1) placed on the area to be treated, 2) secured if required, and then and only then 3) the system is activated and treatment begun. This greatly reduces 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. Treatment protocol standards do dictate power settings be adjusted for the patient's Fitzpatrick Scale skin type; as differing skin tones result in a variance in their coefficient of absorption of photonic energy. If these recommendations are not followed the therapy may result in skin sensitivity. Additionally each patient is asked to verbally attest to his or her comfort level at the start of each therapy session and further instructed to notify staff of any skin discomfort at any time during the treatment.

Staff and Investigator Training and Certification

All staff involved in conducting the clinical trial will undergo training and be certified on the use, safety, and clinical procedures of the invisa-RED Technology IR REHAB device. The Primary Investigator and clinical associates conducting the trial will also successfully complete the Collaborative Institutional Training Initiative (CITI) course GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus).

Statistical Analysis Plan

for the clinical study

"Clinical Trial to Establish the Safety and Efficacy of the IR REHAB Device When Used as an Adjunctive Therapy for Nociceptive Musculoskeletal Pain"

FDA Study NCT06393088

Study Research Questions

Research Question:

Is there a statistically significant difference in nociceptive musculoskeletal pain after therapy with the IR REHAB device as compared to a sham (placebo) device when used in an approved and standardized clinical protocol?

Null Hypothesis:

There is not a statistically significant difference in nociceptive musculoskeletal pain when using an IR REHAB device when compared with a sham (placebo) device as a therapy in an approved and standardized clinical protocol.

Alternative Hypothesis:

There is a statistically significant difference in nociceptive musculoskeletal pain when using an IR REHAB device when compared with a sham (placebo) device as a therapy in an approved and standardized clinical protocol.

Data Sets/Populations

Criteria for Participants:

Participants will be taken from a random population of respondents to email and social media recruitment, in person offers to participate to existing patients, and individuals in the community who have seen signage advertising the trial. The number of participants is projected to be thirty (30). There will be an equitable distribution of male and female participants. Women who are pregnant, trying to get pregnant, or nursing will be excluded from the study, as they should not receive Low-level Laser Therapy (LLLT). Note; 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 such individuals. The participants will be older than the age of 18 years. Inclusion criteria will be individuals that may benefit from an adjunctive therapy for nociceptive musculoskeletal pain.

Exclusion criteria will include the following:

- For women who 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 against treatment during these times.

- 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.

- Person with 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.

- A person with a history of erythema, an acquired, long-lasting reticulocyte red and pigmented rash, caused by persistent or repeated exposure to intense heat or infrared radiation.

- Persons who are susceptible to or have a history of herpes in the treatment area

- Anyone who has experienced problems subsequent to previous laser treatments

- 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

- 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.

- People who have used isotretinoin (commonly known as Accutane), tetracycline, St. John's Wort, or any photo sensitizing drugs in the last year should not undergo laser light therapy.

- Individuals with autoimmune diseases such as Lupus, Scleroderma, or Vitiligo should not undergo laser light therapy.

Exclusion Criteria - continued

- 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.

- All individuals considered “vulnerable” such as children, pregnant women, nursing home residents or other institutionalized persons, students, employees, fetuses, prisoners, and persons with decisional incapacity.

Analysis

To examine the research question, independent sample *t*-tests using the statistical analysis program IBM SPSS ver.30 will be conducted on the data set. The data set will be comprised of comparative results from the two trial groups, the Care as Usual Study Group and the Sham (placebo effect) Study Group. The tests will be bootstrapped to a test size of N=20,000 for validation.

An independent samples *t*-test is the appropriate statistical test when the purpose of research is to assess if differences exist on a continuous (interval/ratio) dependent variable by a dichotomous (2 groups) independent variable. The continuous dependent variable to be tested is the change in pain level of the joint or body area treated during the clinical trial. Each participant will be asked to indicate on a standard 100mm Visual Analog Scale their pain levels before the first treatment and after each of the prescribed treatments. The difference between the initial pain level of a participant and the level of pain indicted after their sixth and final treatment will be statistically analyzed to determine if there is a significant difference between those in the Care As Usual Group and the Sham (placebo) Group.

The dichotomous independent variables for the data set is the change in pain level of each participant in the group treated with the invisa-RED Technology IR REHAB Low-level Laser Therapy (LLLT) device and the group treated using the sham (placebo) device as a therapy in the standardized clinical protocol. The assumptions of normality and homogeneity of variance will be assessed. Homogeneity of variance assumes that both groups have equal error variances and will be assessed using Levene’s Test for the Equality of Error Variances. Each t-test will be two tailed with the probability of rejecting the null hypothesis when it is true set at $p < 0.05$. This ensures a 95% certainty that the differences did not occur by chance. Data produced by both groups will be the results of a clinical trial governed and conducted as a randomized single - blind study using an IRB approved clinical protocol.

Requirements for Human Subject Protection Training

The Primary Investigator and clinical associates conducting the trial will complete the Collaborative Institutional Training Initiative (CITI) course GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus).

Recruitment
The Trial recruitment period had a start date of July 22nd and ended on August 7th 2024. (A total of 17 days) All participant recruitment and interviews were conducted at the Abbycare Clinic in Woodstock, GA.

Reporting Groups
The first was the **IR REHAB Group** which was a randomly selected group of sixteen (16) participants who received treatment per the prescribed trial protocol using a fully functional invisa-RED Technology IR REHAB device. Treatment protocol is as follows: Participants will undergo six (6) therapy sessions of 15 minutes each over a three week period. Power settings will be based on the participants Fitzpatrick Scale skin type. For skin types i and ii a power setting of 7 was used, for skin types iii and iv a power setting of 6, for skin types v and vi a power setting of 4 was employed. Each participant randomly assigned to the IR REHAB group underwent six therapy sessions over three weeks using a fully functional invisa-RED Technology IR REHAB device.

The second group was the **Sham Group** which was a control group of thirteen (13) randomly selected participants who received a placebo treatment per the prescribed trial protocol using a non functional IR REHAB device. (The sham device was disabled and delivered no Low-level Laser Light energy during therapy but appeared to be fully functioning and powered-up.) Treatment protocol was as follows: Participants underwent six (6) therapy sessions of 15 minutes each over a three week period. Power settings were input based on the participants Fitzpatrick Scale skin type as per usual. For skin types i and ii a power setting of 7 was input, for skin types iii and iv a power setting of 6, for skin types v and vi a power setting of 4 was utilized. Each participant randomly assigned to the "Sham Group" underwent six therapy sessions over three weeks using the sham (non functioning invisa-RED Technology IR REHAB) device.

Participant Flow:

Recruitment Details	The Trial recruitment period had a start date of July 22nd and ended on August 7th 2024. (A total of 17 days) All participant recruitment and interviews were conducted at the Abbycare Clinic in Woodstock, GA.
Pre-assignment Details	

Arm/Group Title	IR REHAB Device	Sham Device	Total (Not public)
▸ Arm/Group Description	Participants will receive 6 treatme...	Participants will receive 6 treatme...	
Period Title: Overall Study			
Started	16	15	31
Completed	16	13	29
Not Completed	0	2	2
Reason Not Completed			
Withdrawal by Subject	0	2	2
(Not Public)	Not Completed =0 Total from all reasons =0	Not Completed =2 Total from all reasons =2	

Baseline Characteristics:

Arm/Group Title		IR REHAB Device		Sham Device		Total	
▾ Arm/Group Description		Participants will receive 6 treatments of 15 minutes each with an active IR REHAB device over the period of three weeks. IR REHAB: Participants undergo therapy sessions with active, dual wavelength, low level laser therapy device		Participants will receive 6 treatments of 15 minutes each with a disabled (sham) IR REHAB device over the period of three weeks. Sham: Participants undergo therapy sessions with disabled device producing no laser energy			
Overall Number of Baseline Participants		16		13		29	
▾ Baseline Analysis Population Description [Not specified]							
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	16 participants		13 participants		29 participants	
	<=18 years	0	0%	0	0%	0	0%
	Between 18 and 65 years	11	68.75%	12	92.31%	23	79.31%
	>=65 years	5	31.25%	1	7.69%	6	20.69%
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	16 participants		13 participants		29 participants	
	Female	6	37.5%	6	46.15%	12	41.38%
	Male	10	62.5%	7	53.85%	17	58.62%
Race/Ethnicity, Customized Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	16 participants		13 participants		29 participants	
Race	White	13	81.25%	8	61.54%	21	72.41%
	Black	2	12.5%	4	30.77%	6	20.69%
	Hispanic	1	6.25%	0	0%	1	3.45%
	Other	0	0%	1	7.69%	1	3.45%
IR REHAB Clinical Trial Participants Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	16 participants		13 participants		29 participants	
		16	100%	13	100%	29	100%

Outcome Measures:

1. Primary Outcome

Title:	Measured Change in the Participants Pain Levels
▸ Description:	Participants pain levels will be measured using a visual analog scale ... If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.
Time Frame:	Participants will indicate their pain level before and after each of six therapy sessions over a period of three weeks

▾ Outcome Measure Data ✓

▸ Analysis Population Description

Arm/Group Title	IR REHAB Device	Sham Device
▸ Arm/Group Description:	Participants will receive 6 treatme...	Participants will receive 6 treatme...
Overall Number of Participants Analyzed	16	13
Mean (95% Confidence Interval) Unit of Measure: Score on a scale	61.46 (47.70 to 72.63)	19.79 (4.89 to 37.34)

Outcome Measures - continued:

Delete

Statistical Analysis Overview	Comparison Group Selection	IR REHAB Device, Sham Device
	Comments	Null Hypothesis: There is not a statistically significant difference in nociceptive musculoskeletal pain when using an IR REHAB device when compared with a sham (placebo) device as a therapy in an approved and standardized clinical protocol.
	Type of Statistical Test	Superiority
	Comments	It was calculated that 24 participants randomized 1:1 between 2 arms would have at least an 85% power to detect a difference in pain relief of 30 points as measured using a Visual Analog Device. The actual difference in the mean of the change in pain level, as measured using a Visual Analog Scale, between the two independent groups is 41.67. Results of the post trial calculation was a 95.7% power to detect the difference in pain relief using 29 randomized participants.
Statistical Test of Hypothesis	P-Value	<0.01
	Comments	The threshold is P-value <.0.05 for statistical significance A bootstrap N=20,000 was used for all estimates
	Method	t-test, 2 sided
	Comments	[Not specified]
Method of Estimation	Estimation Parameter	Mean Difference (Net)
	Estimated Value	41.67
	Confidence Interval	(2-Sided) 95% 20.15 to 61.67
	Estimation Comments	[Not specified]

Adverse Effects Overview:

Edit	Time Frame	4 months
	Adverse Event Reporting Description	
	Source Vocabulary Name for Table Default	[Not specified]
	Collection Approach for Table Default	Non-systematic Assessment

Edit	Arm/Group Title	IR REHAB Device	Sham Device
	▼ Arm/Group Description	Participants will receive 6 treatments of 15 minutes each with an active IR REHAB device over the period of three weeks. IR REHAB: Participants undergo therapy sessions with active, dual wavelength, low level laser therapy device	Participants will receive 6 treatments of 15 minutes each with a disabled (sham) IR REHAB device over the period of three weeks. Sham: Participants undergo therapy sessions with disabled device producing no laser energy

All-Cause Mortality

		IR REHAB Device	**Sham Device**
		Affected / at Risk (%)	Affected / at Risk (%)
Edit	Total	0/16 (0%)	0/13 (0%)

▼ Serious Adverse Events

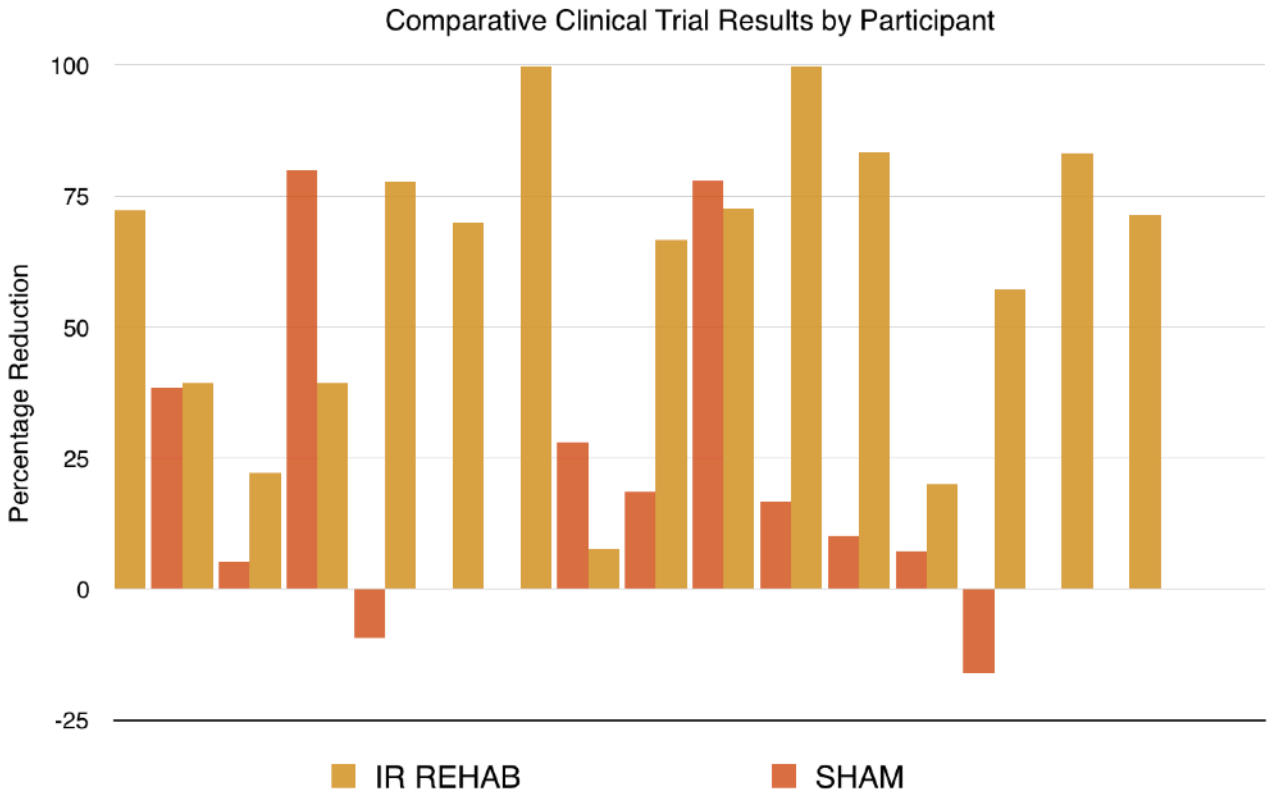
		IR REHAB Device	**Sham Device**
		Affected / at Risk (%)	Affected / at Risk (%)
Edit	Total	0/16 (0%)	0/13 (0%)

Add Serious Adverse Event

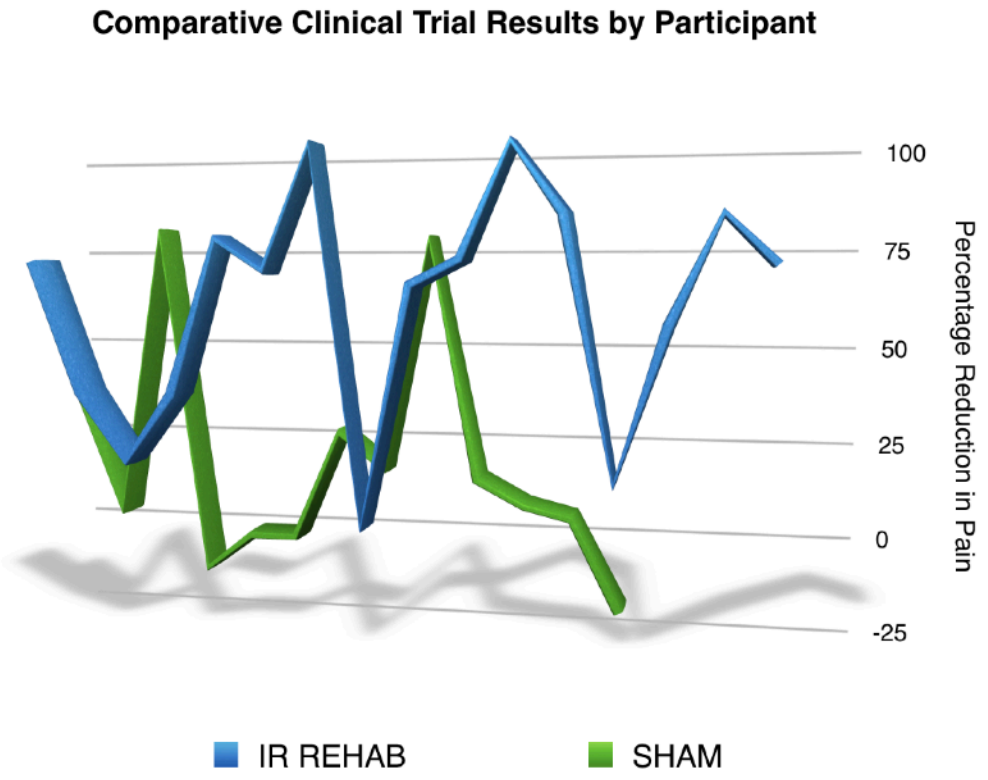
▼ Other (Not Including Serious) Adverse Events

Edit	Frequency Threshold for Reporting Other Adverse Events	0%	
		IR REHAB Device	**Sham Device**
		Affected / at Risk (%)	Affected / at Risk (%)
Edit	Total	0/16 (0%)	0/13 (0%)

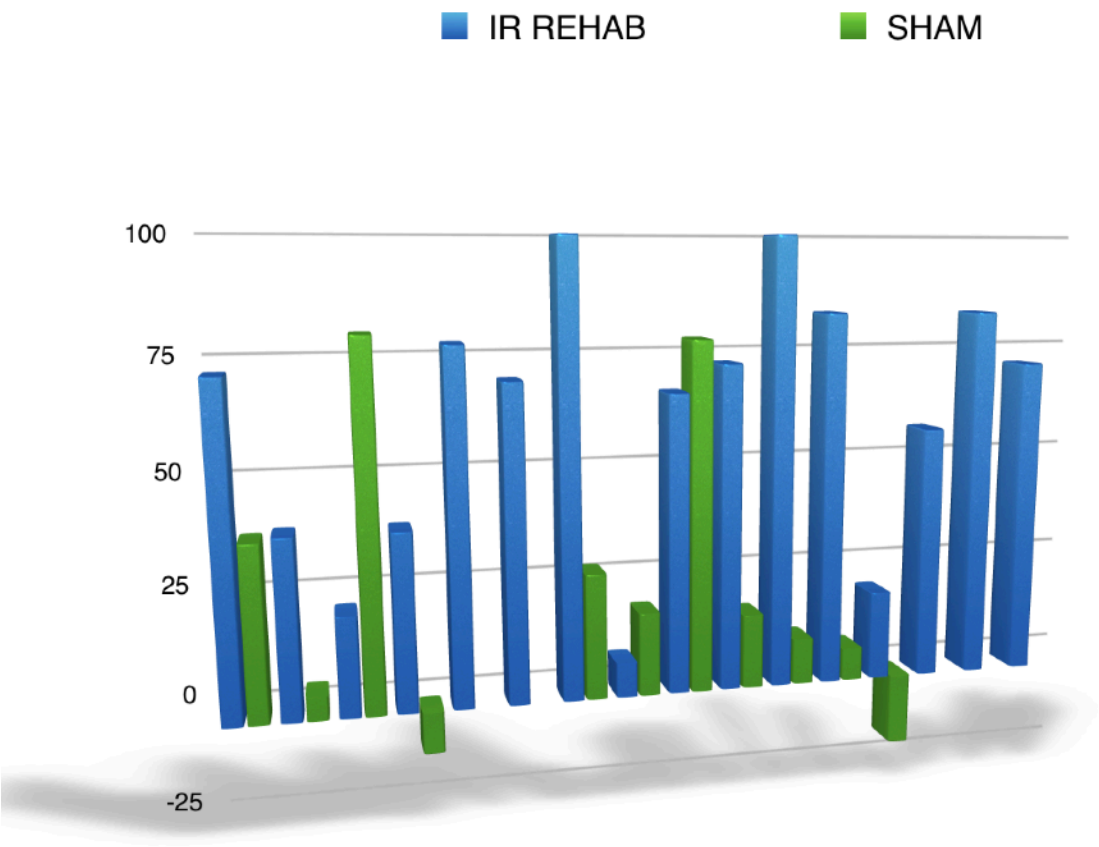
Graphs Depicting Results:



Graphs Depicting Results - continued:



Graphs Depicting Results - continued:



Study Results

The “Clinical Trial to Establish the Safety and Efficacy of the IR REHAB Device When Used as an Adjunctive Therapy for Nociceptive Musculoskeletal Pain” FDA Study NCT06393088, was designed to provide data with which to evaluate the efficacy and safety of the invisa-RED® IR REHAB Low-level Laser Therapy (LLLT) device as compared with a sham device when used for the adjunctive treatment of musculoskeletal pain . This single blind trial of two groups; one group treated as usual, the other treated using a sham device. At the conclusion of the trial; results from the two groups were statistically analyzed to determine the efficacy and safety of the invisa-RED® IR REHAB machine for the adjunctive treatment of nociceptive musculoskeletal pain.

The study was designed as a superiority trial with a null hypotheses which asserted, in the population where the sample was obtained there was no difference between the intervention (IR REHAB) and placebo (Sham Device) groups in the mean change in the primary outcome variable:

However, the results of a bootstrapped (N=20,000) independent samples 2 sided t-test revealed:

> An estimated mean difference (net value) of 41.67% greater reduction in participant’s pain level when using the invisa-RED® IR REHAB as compared to the Sham Device this with a 95% confidence level from 20.15% to 61.67% and a two tailed P value < 0.01.

Therefore by conventional criteria the results are considered to be statistically significant for the trial's primary outcome variable, disproving the null hypotheses and affirming the alternative hypotheses that there exists an interventional superiority of the invisa-RED® IR REHAB therapy over the Sham Device (placebo).

Additionally and of great significance, there were zero adverse effects or mortality reported during or after the the clinical trial.

Three additional bootstrapped analysis (N=20,000) of the data were conducted:

1) An independent samples effect size analysis was conducted using Cohen's d and resulted in a value of 1.44, which by convention indicates a large effect size for the invisa-RED® IR REHAB over a placebo.

2) A Mann-Whitney U test was performed to evaluate whether results differed by treatment group. The results also indicated that the group treated with the invisa-RED® IR REHAB had significantly greater pain reduction than those treated with the Sham Device, $z = [-3.12]$, $p = [<0.01]$.

3) Levene's test showed that equal variances for the IR REHAB and Sham Device Groups may be assumed, $F(1,27) = .006$, $p = .936$.

Conclusions That May Be Drawn From The Study

A conclusion may be made that there is an interventional superiority of the invisa-RED® IR REHAB over a Sham (placebo) device when employed as a therapy for the adjunctive treatment of nociceptive musculoskeletal pain, and that the invisa-RED® IR REHAB when used as directed is both clinically safe and effective.