Low Level Laser Therapy to Reduce Chronic Pain

ClinicalTrials.gov Identifier: NCT00929773

Recruitment Status: Completed
First Posted: June 29, 2009
Results First Posted: May 2, 2014
Last Update Posted: May 2, 2014

Sponsor:
Erchonia Corporation

Information provided by (Responsible Party):
Erchonia Corporation

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Triple (Participant, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Chronic Pain
Interventions:	Device: Erchonia PL2000 Laser Device: Placebo laser

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Recruitment period was July through September, 2000 at a single medical clinic.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Following enrollment and prior to group assignment, study participants underwent study qualification evaluation which included a self-report rating of current neck and/or shoulder pain level on the 0-100 VAS.

Reporting Groups

	Description
Erchonia PL2000 Laser	Low level laser energy comprised of 1 milliWatt (mW) of near-infrared light (635 nm) to the neck and shoulder area .
Placebo Laser	inactive light

Participant Flow: Overall Study

	Erchonia PL2000 Laser	Placebo Laser
STARTED	**50**	**50**
COMPLETED	**50**	**50**
NOT COMPLETED	**0**	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Erchonia Low Level Laser Therapy	Low level laser energy comprised of 1 mw of near-infrared light (635 nm) to the neck and shoulder area .
Placebo Laser	inactive light
Total	Total of all reporting groups

Baseline Measures

	Erchonia Low Level Laser Therapy	Placebo Laser	Total
Overall Participants Analyzed [Units: Participants]	**50**	**50**	**100**
Age [Units: Participants]			
<=18 years	**0**	**0**	**0**
Between 18 and 65 years	**50**	**50**	**100**
>=65 years	**0**	**0**	**0**
Gender [Units: Participants]			
Female	**25**	**25**	**50**
Male	**25**	**25**	**50**

Location of Pain [1] [Units: Participants]			
Shoulders	**10**	**14**	**24**
Neck	**13**	**14**	**27**
Neck & Shoulders	**27**	**22**	**49**
[1] Subject report of pain located in the neck, shoulder or both regions.			
Type of Pain [Units: Participants]			
Chronic	**43**	**44**	**87**
Acute	**7**	**6**	**13**
Pain Rating on the Visual Analog Scale (VAS) [1] [Units: Units on a scale] Mean (Standard Deviation)	**51.14 (16.50)**	**49.06 (19.48)**	**50.10 (18.00)**
[1] The Visual Analog Scale (VAS) is used as a self-reported measure of current pain level. Participants mark the spot on the line scale that shows the level of their pain at that time. The scale ranges fron '0: no pain at all' to '100: worst pain imaginable.' The scale is a straight line of 100mm. The point marked by the participant is measured as their current pain level. The higher the number, the greater the pain level. To qualify to be in the study, participants needed to record a Baseline pain level on the VAS of 30 or greater.			
Duration of Pain [Units: Months] Mean (Standard Deviation)	**57.11 (121.40)**	**40.25 (71.13)**	**48.15 (97.64)**

Outcome Measures

Show All Outcome Measures

1. **Primary: Number of Participants Whose Self-reported Degree of Pain on the Visual Analog Scale (VAS) in the Neck and Shoulder Area Decreased by 30% or More From Before to After Study Treatment. [Time Frame: baseline and one hour]**

   Show Outcome Measure 1

2. **Primary: Change in Self-reported Degree of Pain in the Neck-shoulder Region on the 0-100 Visual Analog Scale (VAS) [Time Frame: baseline and one hour]**

   Show Outcome Measure 2

3. **Secondary: Change in Range of Motion (ROM) for the Left Side of the Neck From Baseline to One Hour After Study Treatment. [Time Frame: baseline and one hour]**

   Show Outcome Measure 3

4. **Secondary: Change in Range of Motion (ROM) for the Left Shoulder From Baseline to One Hour After Study Treatment. [Time Frame: one hour]**

   Show Outcome Measure 4

5. **Secondary: Change in Range of Motion (ROM) for the Right Side of the Neck From Baseline to One Hour After Study Treatment. [Time Frame: baseline and one hour]**

   Show Outcome Measure 5

6. Secondary: Change in Range of Motion (ROM) for the Right Shoulder From Baseline to One Hour After Study Treatment. [Time Frame: baseline and one hour]

Show Outcome Measure 6

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There is **NOT** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

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