Low Level Laser Therapy to Reduce Chronic Pain

This study has been completed.

First Received on June 25, 2009. Last Updated on June 26, 2009 History of Changes

Sponsor:	**Erchonia** Corporation
Information provided by:	Erchonia Corporation
ClinicalTrials.gov Identifier:	NCT00929773

Purpose

The purpose of this study was to determine whether low level laser light directed at the neck and shoulders could be effective in the temporary reduction of chronic pain in the neck and shoulder region.

Condition	Intervention
Chronic Neck Pain Shoulder Pain	Device: **Erchonia** PL2000 Laser Device: Placebo laser

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Study of the Effect of Low Level Laser Light Therapy on the Reduction of Chronic Pain of the Neck and Shoulders

Resource links provided by NLM:

MedlinePlus related topics: Chronic Pain Neck Injuries and Disorders

U.S. FDA Resources

Further study details as provided by Erchonia Corporation:

Primary Outcome Measures:

- Degree of pain in the neck and shoulder region [Time Frame: one hour]

[Designated as safety issue: No]

Secondary Outcome Measures:

- Linear range of motion for the right and left sides of the neck and shoulder
  [Time Frame: one hour] [Designated as safety issue: No]

Enrollment:	100
Study Start Date:	July 2000
Study Completion Date:	September 2000
Primary Completion Date:	September 2000 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: **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 .	Device: **Erchonia** PL2000 Laser Low level laser therapy device that emits 1 mw of red (635 nm wavelength) light via an electric diode energy source (CDRH Class II). It is a hand-held device that uses rechargeable batteries or a separate AC power adapter. Other Names: • **Erchonia** PL5000 • **Erchonia** EVRL Laser
Placebo Comparator: Placebo laser inactive light	Device: Placebo laser Inactive laser light.

Detailed Description:

Chronic neck and shoulder pain arising from osteoarthritis, chronic muscle spasms or thoracic or cervical spine sprain strain can be seriously debilitating. Currently available treatment options such as pain relief medication, ice pack, massage, physical therapy and chiropractic are typically of limited effectiveness. More permanent options such as surgery are invasive with long recovery periods and side-effects and complications of their own. Low level laser light therapy, with its proven anti-inflammatory ability, offers a simple non-invasive option for the reduction of chronic neck and shoulder pain.

Eligibility

Ages Eligible for Study:	18 Years to 65 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Muscular-skeletal pain in the neck/shoulder region
- Acute and chronic pain in the neck/shoulder region
- Restricted range of motion in the neck/shoulder region
- Fibrosis or scar tissue in the neck/shoulder region
- Inflammation in the neck/shoulder region
- Altered function in the neck/shoulder region
- Muscle strains in the neck/shoulder region
- 30 or greater on the 0-100 VAS pain scale

- 18-65 years of age

Exclusion Criteria:

- Severely herniated disks
- Pregnancy
- Taken pain medication within the past 12 hours

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00929773

Sponsors and Collaborators

Erchonia Corporation

Investigators

Principal Investigator:	Richard Amy, DC
Principal Investigator:	George Gonzalez, DC
Principal Investigator:	John Pinto, DC
Principal Investigator:	Allen Wentworth, DC
Principal Investigator:	Robert Stashko, DC

More Information

Additional Information:

FDA 510(k)#K050672 clearance listing for pain reduction EXIT

FDA 510(k)#K012580 clearance based on these study results EXIT

No publications provided

Responsible Party:	Mr. Steven Shanks, Erchonia Medical, Inc.
ClinicalTrials.gov Identifier:	NCT00929773 History of Changes
Other Study ID Numbers:	ECP-001
Study First Received:	June 25, 2009
Last Updated:	June 26, 2009
Health Authority:	United States: Institutional Review Board

Additional relevant MeSH terms:

Neck Pain	Signs and Symptoms
Shoulder Pain	Arthralgia
Pain	Joint Diseases
Neurologic Manifestations	Musculoskeletal Diseases
Nervous System Diseases	

ClinicalTrials.gov processed this record on September 05, 2012


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