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The effectiveness of therapeutic laser treatment for elbow tendonitis (tennis elbow)

Submission date
09/01/2013

Recruitment status
No longer recruiting

Registration date
16/01/2013

Overall study status
Completed

Last Edited
25/08/2015

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Tendonitis (inflammation of a tendon) is a very common condition for which there is still no reliable treatment. One method which has shown promise is low level laser therapy (LLLT), however the findings from studies examining the ability of LLLT to lessen the pain, loss of strength and dysfunction of tendonitis are not clear. Recently, a new higher power laser instrument has been developed which is capable of delivering a dose much faster. Thus, the purpose of this investigation was to determine the effectiveness of this new instrument for the treatment of one specific type of tendonitis (tennis elbow or lateral epicondylitis).

Who can participate?
Participants were recruited by advertisement in the newspaper in Toledo Ohio in the fall of 2009. Only otherwise healthy volunteers with tennis elbow were accepted, about half of them were women and half were men. The average age was around 50 years of age, and most of them had suffered from tendonitis of the elbow for over 2 years.

What does the study involve?
Once participants had been checked by a physician to make sure that they had tendonitis of the elbow they were randomly assigned to one of two groups. Group A received the true treatment, group B received a treatment from an identical machine but instead of a laser it had a regular light. None of the doctors or patients knew which machine was which, there was no way to tell the difference between the two. Each treatment took about 10 minutes, and there were 8 treatments in total over three weeks. No one was allowed to use other types of treatments during the study. At the end of the treatment series the participants were checked again for signs of tendonitis including pain, strength, function and an ultrasound. They came back three more times over the next year to see if their elbows still felt better. After 3 months though, the participants who were in group B were offered the chance to try the real laser. The study concluded in January of 2011.

What are the possible benefits and risks of participating?
The benefits to participating in this study were the opportunity to help find an effective treatment for elbow tendonitis and to receive this treatment free of charge. The risks of the treatment are very low. The laser is powerful enough to damage a person's eyes, but

participants were given protective goggles to wear. There were no side effects from the treatments.

Where is the study run from?
The study was run from Selkirk College Castlegar British Columbia Canada, but recruitment, treatment and data collection were only run at one location, ProMedica Sports Care (primary care) facility in Toledo Ohio USA.

When is the study starting and how long is it expected to run for?
We began recruitment in September 2009 and completed the last follow up evaluations in January 2011. We recruited subjects for 4 months up until December 2009.

Who is funding the study?
The study was funded by the manufacturer of the laser, LiteCure LLT, but they were not involved in the study design or in the analysis and reporting of any of the data.

Who is the main contact?
Dr Delia Roberts
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

The efficacy of therapeutic class IV laser treatment for epicondylitis: a randomized controlled trial

Study objectives
We hypothesize that when administered in eight treatments over 21 days with a total dose per treatment of 3000 J (6.6 ± 1.3 J/cm2) therapeutic class IV laser therapy will be effective in a clinical setting for the long term alleviation of the pain, loss of strength and dysfunction of tendinopathy of the extensor carpi radialis brevis tendon.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ProMedica Health System Institutional Review Board. #09-005, 29/07/2009. Continuation received 29/01/2010.

Study design
Randomized double-blinded placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Tendinopathy of the extensor carpi radialis brevis tendon

Interventions
The area to be treated was demarcated at ½ the distance from the lateral epicondyle to the ulnar styloid process and 1/3 of the distance from the lateral epicondyle to the acromion process. The laser probe was kept perpendicular to, and approximately 2.5 cm above the surface of the dermis, creating a spot size 5.7 - 9.6 cm2. The laser was set at full power (600J/min) with a continuous wave form generating a total dose per treatment of 3000 J in 5 min or 6.6 ± 1.3 J /cm2. The first 2.5 minutes of the laser treatment were administered with the arm in full extension, and the second 2.5 minutes were administered while passively moving the joint through its range of motion. Half of the treatment was delivered along the long axis to the tendon, with the other half delivered transverse to the tendon while covering the anterior, lateral and posterior aspects of the lateral epicondyle.

The treatment schedule was as follows: three treatments on consecutive days, four additional treatments over the next ten days and one final treatment during the third week.

The placebo control instrument was a sham machine which appeared identical to the true laser in every way, however the laser had been disabled and only the aiming beam (incandescent light) was functioning.

Intervention Type
Device

Primary outcome measure
The primary outcome measures included both subjective and objective measures to indicate a restoration of strength and function of the extensor carpi radialis brevis tendon from pre-treatment to pre-injury levels. All evaluations were performed by blinded Sport Medicine physicians pre-treatment (baseline), immediately post-completion of the treatment series, and again at three months, six months and 12 months post-treatment. These measures included:
1. Reduction in the rating of pain at rest on using the Visual Analogue Scale (VAS) score (0 = no pain, 10 = unbearable pain)
2. Increased strength on extension (scale of 1-5 with 5 being full strength), and strength on flexion from three maximal trials using the using the Smedley III Digital Grip Strength Tester (in kg)
3. Pain during maximal contractions was also rated using the VAS 10-point scale

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/09/2009

Completion date
28/01/2011

Eligibility

Key inclusion criteria
1. Adults (between the ages of 18 and 65 years of age), either sex
2. Diagnosis of epicondylitis due to injury to the extensor carpi radialis brevis tendon

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
15

Key exclusion criteria
1. Individuals with tattoos, melanoma or pigmented areas around the treatment area
2. Those taking corticosteroids
3. Pregnant
4. With hemorrhagic or cardiac disease
5. Photosensitivity
6. Individuals who had the extensor carpi radialis brevis tendon injected within 3 months prior to the study were also excluded to ensure that there was no influence of prior treatment on the current investigation

Date of first enrolment
01/09/2009

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Canada

Study participating centre
Selkirk College
Castlegar British Columbia
Canada
V1N 4L3

Sponsor information

Organisation
ProMedica Health Systems Sports Care (USA)

Sponsor details
c/o Dr. Roger Kruse
Sports Care
Wildwood Medical Center
2865 N. Reynolds Road, Ste. 110
Toledo Ohio
United States of America
43615

Sponsor type

Research organisation

Website
http://www.promedica.org/sportscare

Funder(s)

Funder type
Industry

Funder Name
LiteCure LLC (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2013		Yes	No