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The efficacy of Low Level Laser Therapy (LLLT) in knee osteoarthritis

Submission date
23/01/2013

Recruitment status
No longer recruiting

Registration date
05/02/2013

Overall study status
Completed

Last Edited
05/02/2013

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is the most common type of arthritis and is a major cause of disability and impaired quality of life in the elderly. In recent years, this problem extended to affecteven younger people. Currently, no disease modifying treatments (DMT) are approved by the Food and Drug Administration or European Medicines Agency for OA. However, large number of treatments is available such as non-steroidal anti-inflammatory drugs, despite its high risks of side-effects in addition to relatively high cost. Low level laser therapy (LLLT) is an intervention (treatment) which is increasingly recognised as a
non-invasive and safe treatment for numerous chronic conditions including OA. Results of using LLLT on patients with knee OA are conflicting. Thus, the purpose of this study was to determine the efficacy of LLLT when applied on specific acupuncture points.

Who can participate?
Any patient with knee OA and diagnosed by his physician and then was referred to physiotherapy department was eligible for the study. Participants were both male and female aged 35 and over.

What does the study involve?
Forty nine participants were randomly assigned to one of the two study groups, group 1 (experimental) received active laser therapy (n= 26) or group 2 (control) received placebo (dummy) laser therapy (n=23). Participants in group 1 received active laser group on five acupuncture points at the affected knee. The same procedures were applied to patients in the placebo
group but rather this time the device was inactive, only producing visible red light. both the investigator and the patient were unaware of whether placebo or active treatment were utilized, only the research assistant had the identifying code to determine which treatment was given.

What are the possible benefits and risks of participating?
One of the most important benefits is finding out alternative, non-invasive, and safe treatment for patients with knee OA, especially relevant for patients who do not respond to medical therapy or those who suffer adverse side-effects to drug therapy and for patients who are not

candidates for surgery.
Despite using LLLT is safe, direct laser on eye can cause damage, thus, in the current study the investigator, research assistant and patients wore protective goggles to guard their eyes from active laser radiation.

Where is the study run from?
The study was carried out at Physiotherapy Department of Security Forces Hospital in Riyadh, Saudi Arabia

When is the study starting and how long is it expected to run for?
Patient recruitment started in September 2010, and last follow-up assessment was done in February 2011.

Who is funding the study?
The project was funded by general administration for medical services of Ministry of Interior, Security Forces Hospital; Riyadh, Saudi Arabia.

Who is the main contact?
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Contact information

Type(s)
Scientific

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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 Low Level Laser Therapy (LLLT) in knee osteoarthritis: A randomized double-blind controlled trial

Study objectives
We hypothesized that when low level laser is administrating on specific acupuncture points on patients with knee osteoarthritis for nine treatment sessions over three weeks will be effective in relief their pain and improve quality of the life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Research Committee of the Security Forces Hospital, March 8, 2010

Study design
Randomized double blinded placebo controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Knee osteoarthritis

Interventions
On the affected knee, the laser probe was sequentially and perpendicularly placed in a full contact with the skin at five acupuncture points on and around the affected knee. In the active laser group, each point was irradiated by an active and continuous laser beam for 40 seconds (energy density of 4 J/ cm2 per point, total of 20 J/cm2 per session) for each patient. This dose was in accordance with World Association for Laser Therapy recommendations. The same procedures were applied to patients in the placebo group but rather this time the device was inactive, only producing visible red light.

In both groups, patients were given a straight leg raising (SLR) exercise to perform after each treatment session and they were advised to repeat it at home five times daily, minimally.

Patients in both groups were given helpful advice and instructions regarding their problem and how they should be managing and coping with Knee OA.

Each participant received 9 treatment sessions over 3 weeks and they were evaluated at baseline, at the 5th treatment session, at the 9th treatment session (last treatment session), after 6 weeks, and after 6 months of the last treatment session.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The change in the VAS scores for pain during movement. It consists of a 10 cm line anchored at each end (0 = no pain, 10 = unbearable
pain). All evaluations for both primary and secondary outcomes were administrated at the 5th treatment session, at the 9th treatment session, after 6 weeks, and after 6 months of the last treatment session. All evaluations were performed by the investigator.

Secondary outcome measures
1. The Saudi knee functional scale (SKFS): It is a multidimensional self-administered, and Arabic language instrument that emphasises pain (8 items), stiffness (2 items), physical function activities (12 items), social activities (3 items), and psychological activities (3 items) related to KOA.
2. The degree of active knee angle flexion: measured by goniometer
3. Knee circumference (KC): was measured using a standard tape measure at the middle of the patella with the knee extended.
4. Patient satisfaction: each participant was asked to rate his satisfied about the intervention that has been received, if he has gotten any benefit. The assessment was performed using a verbal numeric scale (end-points 0% no improvement or benefit to 100% full improvement or benefit; in blocks of 5%). Evaluation started at the 5th session as a baseline, then at , at the 9th treatment session, after 6 weeks, and after 6 months of the last treatment session.

Overall study start date
18/09/2010

Completion date
01/07/2011

Eligibility

Key inclusion criteria
1. Patients who had knee OA (both male and female aged 35 and over) according to the American College of Rheumatology criteria
2. Had an average pain intensity of 3 or more on a 10 cm visual analogue scale (VAS)
3. Had an ability to practice all movements included in the evaluation forms
4. Had the ability to read or understand the patient information sheets and the ability to sign a consent form

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
21 participants for each arm of the study

Key exclusion criteria
1. Patients with previous knee surgery, serious valgus or varus deformity and any disease where laser treatment is contraindicated, such as cancer, uncontrolled diabetes mellitus and hypertension
2. Patients already using medications that may interfere with LLLT treatment for less than six weeks, such as corticosteroid injections

Date of first enrolment
18/09/2010

Date of final enrolment
01/07/2011

Locations

Countries of recruitment
Saudi Arabia

Scotland

United Kingdom

Study participating centre
Department of Orthopaedic and Trauma Surgery
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Sponsor information

Organisation
Security Forces Hospital (Saudi Arabia)

Sponsor details

General administration for medical services of Ministry of Interior
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Sponsor type
Hospital/treatment centre

Website
http://www.sfh.med.sa/English/Pages/Security%20Forces%20Hospital%20Program.aspx

ROR
https://ror.org/035n3nf68

Funder(s)

Funder type
Government

Funder Name
General administration for medical services of Ministry of Interior, Security Forces Hospital; Riyadh (Saudi Arabia)

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		15/11/2013		Yes	No