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Low Level Laser Therapy in meniscal pathology

Submission date
25/03/2012

Recruitment status
No longer recruiting

Registration date
25/04/2012

Overall study status
Completed

Last Edited
23/10/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Background and study aims:
At present, Low Level Laser Therapy (LLLT) is used to improve wound healing, reduce pain and swelling, and increase the general rate of recovery after a musculoskeletal injury. LLLT has not yet been used to manage knee injuries. The aim of the study was to see how effective LLLT is when used in patients with knee pain.

Who can participate?
Patients with knee injuries and have experienced knee pain for more than 6 weeks.

What does the study involve?
Using LLLT twice per week for the first three weeks, and once per week for the next three weeks (a total of 9 sessions).

What are the possible benefits and risks of participating?
Improvement of symptoms. There are no known risks of participating in the study

Where is the study run from?
Thessaloniki Sports Medicine Clinic, Greece

When is study starting and how long is it expected to run for?
The study started on 1st January 2009 and finished on 28th February 2011

Who is funding the study?
Investigator initiated and funded

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
Low Level Laser Therapy in meniscal pathology: a double-blinded placebo controlled trial

Study objectives
Is the application of low level laser therapy (LLLT) effective in patients with knee pain related to meniscal pathology

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Double blind randomised placebo controlled 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Patients with knee pain related to meniscal pathology

Interventions
Patients were randomly assigned to receive LLLT (n=32) twice per week for the first three weeks, and once per week for the next three weeks (giving a total of 9 sessions), or identical placebo therapy (n=32).
LLLT was administered using a GaAs laser with an infrared wave length of 904 nm (Irradia Medical Laser, M/D Laser Professional,Stockholm, Sweden) with four infrared diodes by the same blinded experienced physiotherapist.

On the laser probe, an A/B switch determined whether active (A) or sham irradiation (B) was given. During the procedure, the laser appeared identical for both active and sham irradiation, since there was no visible aiming beam.

Treatment was standard, and continuous irradiation was applied over the anatomic area of the medial meniscus (stationary mode procedure). According to our protocol, the medial meniscus was divided into 2 rows of 10 segments of equal size [spots] each, and each spot was irradiated once per session.

The output of the laser averaged 240 mW (Irradia Medical Laser has a built in sensor for auto-calibration of the optical output before each application); the frequency of the pulse was 2400 Hz [anti-inflammatory frequency) and 700Hz (Healing frequency). The spot area was almost 1 cm2 over the meniscal area, with a power density of 0.24W/cm2. Each patient was treated for 420 seconds per knee and per session [210 seconds using 2400Hz and 210 seconds using 700Hz]. The dose of active treatment was 100.8 J per knee, for a total of 907.2 J per knee.

The knee to treat with the laser probe in switch position A or B was decided by opening an opaque envelope containing patients badge number and a written character A or B. The A/B switch on the laser was switched by a technician, and the medial side was treated every time. Thus the allocation of patients to groups was concealed to patients, physiotherapist, and observer. The code of the A/B switch positions on the laser probe was only known to the technician who was responsible to open envelopes, and to the physiotherapist administered the treatment
Follow up was performed at 6 months and after 1 year.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

1. The subjective knee pain of the 64 symptomatic patients was assessed at baseline and after therapy using a subjective-based 100 mm visual analogue scale (VAS) ranging from 0 (no pain) to 100 (maximal pain) [17]. The pain decreased approximately by 65% four weeks after LLLT
2. Participants were also asked to complete the Lysholm Knee Scoring System (LKS) [18], a knee specific questionnaire evaluating pain, function, and swelling of the knee at baseline and after therapy. Four weeks after LLLT the laser group reported an an increase (improvement) in Lysholm score of [82.5 ± 4.6; range, 77-94)

Secondary outcome measures
All the participants were also asked to complete:
1. The Lysholm Knee Scoring System
2. Quantify their pain using VAS at 6 months and after 1 year

At 6 months only a small percentage of patient [2 of 32 patients (6.25%)] had reported a recurrence of the pain. After 1 year, 5 of 2 patients (15.6%) had reported a recurrence of the pain.

Overall study start date
01/01/2009

Completion date
28/02/2011

Eligibility

Key inclusion criteria
1. We included patients with unilateral medial knee pain for more than six weeks.
2. Magnetic resonance imaging (MRI) inclusion criteria:
2.1. Tiny tears seen only on 0.7 thickness sequences.
2.2. Intrasubstance tears (with spot of Grade 3 SI approaching the articular surface) osteochondral lesions

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
64

Key exclusion criteria
1. Patients with bilateral or lateral knee pain
2. History of major knee trauma or knee surgery
3. Diagnosis of rheumatoid arthritis
4. Hemophilia

5. Amyloidosis
6. Seronegative arthritis
7. Psoriasis or gout
8. MRI Exclusion criteria
8.1 Meniscal tears seen on classic protocols
8.2. Chondromalacia
8.3. SONK Lesions/insufficiency fractures
8.4. Stress fractures

Date of first enrolment
01/01/2009

Date of final enrolment
28/02/2011

Locations

Countries of recruitment
Greece

Study participating centre
Thessaoliniki Sports Medicine Clinic
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Sponsor information

Organisation
Thessaoliniki Sports Medicine Clinic (Greece)

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Sponsor type
Hospital/treatment centre

Website
http://www.sportsmed.gr

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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	23/10/2020	Yes	No