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Pulsed electromagnetic fields in association with home exercise program in the management of patellofemoral pain syndrome.

Submission date
26/01/2015

Recruitment status
No longer recruiting

Registration date
03/02/2015

Overall study status
Completed

Last Edited
03/02/2015

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patellofemoral Pain Syndrome (PFPS) is a common cause of recurrent or chronic knee pain in young adults, affecting the kneecap and cartilage around the joint. It can result in pain at the front of the knee and behind the kneecap. This pain can be severe and sufferers often find it difficult to kneel or squat. Inflammation (swelling) of the knee can also sometimes result with an increase of pro inflammatory cytokines in the synovial (joint) fluid, especially when there is damage to the cartilage at the back of the knee (chondromalacia). The causes are not fully understood but it's thought likely to be due to a number of factors including imbalances in the muscles surrounding the knee, tight hamstrings , short ligaments and general overuse of the joint. Exercise therapy, including a home exercise program (HEP) has been shown to be of benefit to sufferers of PFPS. Biophysical stimulation with pulsed electromagnetic fields (PEMFs) has been shown to stimulate cell growth and repair, including in cartilage cells (chondrocytes), and have anti-inflammatory effects. The purpose of this study is to test whether a combination of HEP and PEMFs is better than HEP alone in the treatment of PFPS.

Who can participate?
Participants aged between 15 and 45 and diagnosed with PFPS.

What does the study involve?
Participants are randomly assigned to one of two groups. Those in group 1 are treated with HEP alone. Those in group 2 are given pulsed electromagnetic fields (I-ONE) therapy 4 hours a day for 60 days along with HEP. All participants are then followed up for a year when their knee function and pain levels are assessed.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Federico II Hospital, Naples (Italy)

When is the study starting and how long is it expected to run for?
May 2010 to March 2012

Who is funding the study?
Federico II Hospital, Naples (Italy)

Who is the main contact?
Dr Andrea Sambri

Contact information

Type(s)
Scientific

Contact name
Dr. Andrea Sambri

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Therapeutic efficacy of pulsed electromagnetic fields in association with home exercise program in the management of patellofemoral pain syndrome: a randomized controlled study at one year follow-up.

Study objectives
We hypothesized that pulsed electromagnetic fields associated with exercises are superior than only exercises in the treatment of patellofemoral pain syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Federico II University “C. Romano” Ethic committee, 03/02/2010

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Patellofemoral pain syndrome is a common cause of knee pain in young adults, especially in females who practice sport activities.

Interventions
Patients affected by patellofemoral pain syndrome will be randomized:
1. Pulsed electromagnetic fields (I-ONE) therapy 4 hours/day for 60 days associated with home exercise program
2. Only home exercise program

The total duration of follow up will be 1 year

Intervention Type
Procedure/Surgery

Primary outcome measure
Function of the knee assessed by Victorian Institute of Sport Assessment score (VISA)

Secondary outcome measures
Pain reduction assessed by:
1. Visual analogue scale (VAS)
2. NSAIDs consumption

Overall study start date
01/05/2010

Completion date
31/03/2012

Eligibility

Key inclusion criteria
1. The presence of at least three of the following symptoms: pain when walking up or down stairs, pain when squatting, pain when running, pain when cycling, pain when sitting with knees flexed for a prolonged time, grinding of the patella, and a positive clinical patellar test (such as Clarke's test or patellar femo-ral grinding test)
2. Untreated pain lasting for more than 3 months
3. Age between 15 and 45 years
4. Informed consent given

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
31

Key exclusion criteria
1. Knee capsular ligament or meniscus tears
2. Previous knee surgery
3. Severe knee varus/valgus deformities (>10°)
4. Lower limbs prosthesis
5. Corticosteroid therapy
6. B.M.I. > 30 kg/m2
7. Infections
8. Rheumatoid arthritis and autoimmune diseases
9. Malignancy
10. Systemic diseases
11. Plateau-patella angle <20° or >30°

Date of first enrolment
01/05/2010

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
Italy

Study participating centre

University Hospital Federico II (Azienda Ospedaliera Federico II)
Napoli
Italy
80131

Sponsor information

Organisation
Federico II University

Sponsor details
Corso Umberto I
Naples
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80138

Sponsor type
University/education

ROR
https://ror.org/05290cv24

Funder(s)

Funder type
University/education

Funder Name
Federico II University (Italy)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request