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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

### Contact details
Rizzoli Orthopaedic Institute
via Pupilli 1
Bologna
Italy
40136

# 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
Italy
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