

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	☐ Prospectively registered ☐ Protocol
Registration date 03/02/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 03/02/2015	Condition category Musculoskeletal Diseases	☐ 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
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Additional identifiers

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

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Pain reduction assessed by:

1. Visual analogue scale (VAS)
2. NSAIDs consumption

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

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

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

ROR

<https://ror.org/05290cv24>

Funder(s)**Funder type**

University/education

Funder Name

Federico II University (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request