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Evaluation of I-ONE therapy in patients undergoing total knee arthoplasty

Submission date
15/02/2013

Recruitment status
No longer recruiting

Registration date
27/02/2013

Overall study status
Completed

Last Edited
25/05/2017

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
Osteoarthritis is a condition that causes joints to become painful and stiff. Osteoarthritis affecting the knee can be treated with total knee arthroplasty (TKA), a surgical procedure in which parts of the knee joint are replaced with artificial parts. A massive growth in the number of TKA is expected in the next few decades all over the world, above all in Europe where the aging of the population will reach the highest level in comparison to the other continents. In the last few decades new materials, design and surgical techniques has increased satisfaction following TKA, but 11–25% of patients notice an improvement but are still not satisfied with their TKA. A satisfactory clinical outcome of TKA can depend on several factors including the type of implant and surgical procedure. After TKA, local joint swelling, inflammation and pain can delay recovery or limit joint function in the long term, and that may ultimately lead to altered posture and reduced mobility. A recent study emphasized the need to control the inflammatory reaction of the joint to surgery. In an attempt to favor recovery after TKA, detailed rehabilitation procedures have been developed including exercise instructions and physiotherapy. Oral Non Steroidal Anti Inflammatory Drugs (NSAIDs) are used to control pain and inflammation in the operated knee. However, their use for periods over 72 hours in older patients must take into account the possible negative side effects on the kidneys and stomach. Pulsed electromagnetic fields delivered with the I-ONE therapy device are a possible approach to control inflammation and manage joint diseases. Studies of patients undergoing knee joint surgery have demonstrated that I-ONE therapy reduces joint swelling, the requirement of NSAIDs to control pain, and the time to recovery, and it is well accepted by patients. The main aim of this study was to test whether treatment with I-ONE therapy, along with standard rehabilitation, could limit pain in the short and long term (36 months after TKA); the other aims are to test whether it reduces swelling immediately after TKA and shortens recovery time.

Who can participate?
Patients aged between 60 and 85 with osteoarthrosis of the knee and scheduled for TKA

What does the study involve?
Participants undergo TKA and afterwards are randomly allocated into two groups. One group is

treated with standard rehabilitation. The other group is treated with standard rehabilitation and I-ONE therapy for 4 hours per day for 60 days. Pain, knee function and knee swelling are measured at the start of the study and after 1, 2, 6 and 36 months.

What are the possible benefits and risks of participating?
I-ONE therapy may improve treatment by reducing joint tissue inflammation with short- and long-term positive benefits for patients. No negative side effects have ever been reported in other studies using the device.

Where is the study run from?
The Orthopedic and Traumatology Operative Unit of Clinic “Città di Parma” (Italy)

When is the study starting and how long is it expected to run for?
February 2008 to December 2012

Who is funding the study?
IGEA (Italy), who provide all the devices at no cost; no other kinds of funding are provided by IGEA SPA

Who is the main contact?
1. Dr Paolo Adravanti
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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
v.01_2013

Study information

Scientific Title
Evaluation of I-ONE therapy in patients undergoing total knee arthoplasty: a prospective randomised controlled trial

Acronym
PITTKA (Post-operative I-One Therapy Total Knee Arthoplasty)

Study objectives
Total knee arthroplasty (TKA) is often associated with a severe local inflammatory reaction which, unless controlled, leads to persistent pain up to one year after surgery. Standard and accelerated rehabilitation protocols are currently being implemented after TKA, but no consensus exists regarding the long-term effects. Biophysical stimulation with pulsed electromagnetic fields (PEMFs) has been demonstrated to exert an anti-inflammatory effect, to promote early functional recovery and to maintain a positive long-term effect in patients undergoing joint arthroscopy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The IRB of the Clinic "Città di Parma", January 2008

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact segreteria@paoloadravanti.com to request a patient information sheet

Health condition(s) or problem(s) studied
Knee osteoarthritis

Interventions
Patients who satisfy inclusion criteria, and receiving a cemented postero-stabilized (PS) TKA with patella resurfacing, are randomised in two groups:
1. Experimental group: standard rehabilitation protocol + I-ONE therapy, post-surgery (within one week), 4 hours/day for 60 days
2. Control group: standard rehabilitation protocol

Intervention Type
Device

Primary outcome measure
Pain, measured using the Visual Analogue Scale (VAS) at baseline, 1, 2, 6 and 36 months

Secondary outcome measures
1. Knee Society Score, involving a clinical evaluation, Knee Score (which assesses pain, range of motion, stability, contracture in bending, active extension deficit, alignment) and a functional evaluation, Functional Score (which examines autonomy in walking, climbing stairs, use of stick or frame)
2. Functional evaluation scale SF-36, which evaluates the patient with 36 questions, 10 of which one physical activity, 4 on role limitations due to physical health, 3 on role limitations correlated to emotional state, 2 on physical pain, 5 on perception of state of general health, 4 on vitality, 2 on social activities, 5 on mental health and 1 on change in state of health
3. Joint swelling, measured with a scale that quantifies the presence of joint swelling evaluated by the operator on palpation by balloting the knee
4. Monitoring of assumption of NSAIDs at all follow-ups

All outcomes assessed at 1, 2, and 6 months.

5. Pain and functional outcomes (modified from KSS) at 36 months

Overall study start date
01/02/2008

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Male and female patients aged between 60 and 85
2. Presenting with an advanced state of knee OA and scheduled for TKA, with varus or valgus deformity not exceeding 20° or 15°, respectively, and with a flexion contracture of less than 15°

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
From 1 to 33

Key exclusion criteria

1. Previous surgery to the same knee
2. Omolateral hip prosthesis
3. Body Mass Index (BMI; kg/m2) >30
4. Rheumatoid arthritis
5. Autoimmune diseases
6. Systemic diseases
7. Cancer and the use of steroids

Date of first enrolment
01/02/2008

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Italy

Study participating centre
Piazza Maestri 5
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Sponsor information

Organisation
IGEA S.p.A (Italy)

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Sponsor type
Industry

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Funder(s)

Funder type
Industry

Funder Name
IGEA (Italy)

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