

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

Submission date 15/02/2013	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 27/02/2013	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 25/05/2017	Condition category Musculoskeletal Diseases	☐ 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

2. Laura Degirolamo

laura.degirolamo@grupposansonato.it

Contact information

Type(s)

Scientific

Contact name

Dr Paolo Adravanti

Contact details

Piazza Maestri 5

Parma

Italy

43100

Additional identifiers

Protocol serial number

v.01_2013

Study information

Scientific Title

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

Acronym

PITTKA (Post-operative I-One Therapy Total Knee Arthroplasty)

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

Primary study design

Interventional

Study design

Prospective randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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
Parma
Italy
43100

Sponsor information

Organisation
IGEA S.p.A (Italy)

ROR
<https://ror.org/01bws2668>

Funder(s)

Funder type
Industry

Funder Name
IGEA (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration