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I-ONE® therapy to improve pain and clinical outcomes after partial knee replacement

Submission date
21/01/2021

Recruitment status
No longer recruiting

Registration date
08/02/2021

Overall study status
Completed

Last Edited
08/02/2021

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
Knee replacement is a worldwide-recognized surgical procedure for the treatment of severe end-stage osteoarthritis (OA) of the knee when medical treatment is not enough to avoid pain and maintain an adequate quality of life. The surgical option for patients with OA in one compartment of the knee only is unicompartmental knee arthroplasty (UKA), or partial knee replacement.

Pulsed electromagnetic field (PEMF) therapy, which uses electrical currents applied to the skin around the joints, has previously been shown to reduce inflammation and pain and to improve mobility following joint replacement surgery.

This trial aims to clinically assess pain relief, knee joint functional, and clinical improvement in patients undergoing UKA stimulated with PEMFs (I-ONE® therapy), compared to standard treatment.

Who can participate?
Participants aged between 60 and 85 years with chronic and debilitating knee pain due to medial compartment osteoarthritis who have undergone unicompartmental knee arthroplasty

What does the study involve?
Participants will be randomly allocated to receive either standard treatment or stimulated with PEMFs (I-ONE® therapy).

Participants will be assessed after 1, 6, 12, and 36 months for clinical outcomes such as pain relief, swelling, joint function, ability to complete daily activities, and consumption of pain-relief medication.

What are the possible benefits and risks of participating?
Participants who receive therapy with I-ONE® will possibly benefit from a reduction of pain, faster recovery, and a decrease in medication intake. It has been previously shown in the clinic that therapy with I-ONE® is able to prevent and/or slow down the degeneration that accompanies surgery (including anterior cruciate ligament reconstruction, cartilage lesions

treated with microfractures under arthroscopy, and in total knee replacement with or without patella prosthesis). All clinical studies of I-ONE® therapy compared to standard care have shown a lower intake of NSAIDs (pain relief) and faster recovery of function. Also in non-surgical treatment of conditions such as spontaneous osteonecrosis and early-stage osteoarthritis of the knee, I-ONE® therapy has been proven to be effective in reducing inflammation and improving the functional recovery of the joint. The positive effects of I-ONE® therapy for both surgical and non-surgical patients were maintained over the long term (2 and 3 years after treatment).

No studies have reported side effects or risks of I-ONE therapy.

Where is the study run from?
IRCCS Istituto Ortopedico Galeazzi (Italy)

When is the study starting and how long is it expected to run for?
From July 2014 to April 2020

Who is funding the study?
IGEA (Italy)

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

Protocol serial number
Protocollo UKA e I-ONE® terapia Vers. 2.0 06/05/2014

Study information

Scientific Title
I-ONE® therapy as an effective completion of medial unicompartmental knee arthroplasty: a prospective randomized controlled trial

Acronym
I-ONE and UKA

Study objectives
1. Patients undergoing medial unicompartmental knee arthroplasty (UKA) stimulated with Pulsed Electromagnetic Fields (PEMFs) using I-ONE® therapy will have greater pain relief compared to a control group
2. Patients undergoing UKA stimulated with PEMFs using I-ONE® therapy will have greater knee joint functional and clinical improvement at one, two, six, twelve and 36 months of follow-up compared to a control group

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/07/2014, Ethics Committee of the Ospedale San Raffaele (Via Olgettina n. 60, 20132 Milano;+39(0)2 2643 2911/3731; ianniello.margherita@hsr.it/tadiello.valeria@hsr.it /cammarano.rita@hsr.it), ref: 86/2014

Primary study design
Interventional

Study design
Single-center prospective randomized parallel-group trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied

Isolated medial unicompartmental knee osteoarthritis

Interventions
At recruitment, participants will be subject to baseline assessment using history and objective examination, Visual Analogue Scale (VAS) for knee pain, Knee swelling assessment, Oxford Knee Score, SF-36 Health Survey, and NSAID Registration.

The participants, at the time of recruitment in the study protocol, will be divided, through a randomization program www.randomization.com into two homogeneous groups of 33 patients each (1:1). In order to obtain two homogeneous groups, the following randomization criteria were defined: sex (F/M), age (50-75 and 75-85), and smoking (yes/no).

The experimental group will undergo biophysical treatment with I-ONE® therapy and one group therapy in addition to standard rehabilitation. Treatment with I-ONE® therapy will begin within 3-7 days of surgery, will last 4 h daily, and will be maintained for 60 days. Treatment will be provided at home or during the period of rehabilitation. The control group will not be subjected to biophysical therapy and will receive standard rehabilitation only.

Both patient groups followed the same rehabilitation protocol, which involves passive mobilization from day one after surgery; from day two, started an active progressive mobilization of the joint and assisted walking with two crutches. Gradually and according to each patient, it was therefore recommended to increase the load during walking, continuing with isometric muscle toning exercises, until the total abandonment of walking aids.

Participants will be followed up for assessment at 1, 2, 6, 12, and 36 months after surgery (+/- 5 days) using the Visual Analogue Scale (VAS) for knee pain, Knee swelling assessment, Oxford Knee Score, SF-36 Health Survey, and NSAID Registration. The total duration of follow-up will be 3 years.

Intervention Type
Other

Primary outcome(s)
1. Pain measured using a Visual Analogue Scale (VAS) at baseline, 1, 2, 6, 12, and 36 months. The scale uses a 10 cm horizontal line corresponding to a scale evaluating the pain, where the left end stands for the complete absence of pain and the right end the maximum possible pain or unbearable pain.

Key secondary outcome(s)
1. Swelling, joint function, and ambulation measured using the Oxford Knee Score (OKS), short Form 36 (SF-36) health survey questionnaire, and circumference of the knee at midpatellar height in the supine position, at baseline, 1, 2, 6, 12, and 36 months
2. Complication of normal daily activities due to knee pain measured using the Modified Cincinnati Rating System Questionnaire at baseline, 1, 2, 6, 12, and 36 months
3. Consumption of Non-Steroidal Anti-inflammatory Drug (NSAID) measured through interviews at baseline, 1, 2, 6, 12, and 36 months

Completion date
12/04/2020

Eligibility

Key inclusion criteria
1. Aged between 60 and 85 years
2. Chronic and debilitating knee pain
3. Medial compartment osteoarthritis, with varus or valgus deformity not exceeding 3° respectively, a range of motion >100° with less than 10° of flexion contracture, integrity of anterior and posterior cruciate ligaments, and intact lateral meniscus

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Previous knee infection
2. Total hip arthroplasties
3. Rheumatoid arthritis, autoimmune and systemic diseases or tumors
4. Severe malalignment
5. Body mass index (BMI) >30 kg/m²
6. Missing data
7. Revision surgery
8. Received previous surgery of the affected knee (except arthroscopy for meniscectomy)

Date of first enrolment
03/11/2014

Date of final enrolment
11/04/2017

Locations

Countries of recruitment
Italy

Study participating centre
IRCCS Istituto Ortopedico Galeazzi
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Sponsor information

Organisation
IGEA (Italy)

ROR
https://ror.org/01bws2668

Funder(s)

Funder type
Industry

Funder Name
IGEA Spa

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from s.setti@igeamedical.com. The datasets generated and/or analysed during the current study during this study will also be included in the subsequent results publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			08/02/2021	No	Yes