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

Submission date 21/01/2021	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
Registration date 08/02/2021	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 08/02/2021	<b>Condition category</b> Musculoskeletal Diseases	<ul><li>Individual participant data</li><li>Record updated in last year</li></ul>

# Plain English summary of protocol

Background and study aims

Knee replacement is a worldwide-recognized surgical procedure for the treatment of severe endstage 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? Riccardo D'Ambrosi, MD riccardo.dambrosi@hotmail.it

# **Contact information**

**Type(s)** Scientific

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# Additional identifiers

**EudraCT/CTIS number** Nil known

**IRAS number** 

**ClinicalTrials.gov number** Nil known

Secondary identifying numbers 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

# Study design

Single-center prospective randomized parallel-group trial

**Primary study design** Interventional

Secondary study design Randomised parallel trial

**Study setting(s)** Hospital

**Study type(s)** Treatment

**Participant information sheet** See additional files

## 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 measure

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.

## Secondary outcome measures

 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
 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
 Consumption of Non-Steroidal Anti-inflammatory Drug (NSAID) measured through interviews at baseline, 1, 2, 6, 12, and 36 months

Overall study start date 17/07/2014

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

# Age group

Mixed

# Sex

Both

## Target number of participants

33 participants per group

## 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 data7. Revision surgery8. 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 Via Galeazzi 4 Milan Italy 20161

# Sponsor information

# Organisation

IGEA (Italy)

Sponsor details

Via Parmenide 10/A Carpi Italy 41012 +39 3406677576 s.setti@igeamedical.com

## Sponsor type

Industry

Website

www.igea.it

ROR https://ror.org/01bws2668

# Funder(s)

Funder type Industry

#### **Funder Name** IGEA Spa

# **Results and Publications**

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. The study protocol is available upon request from s.setti@igeamedical.com

#### Intention to publish date

25/04/2021

## 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

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