

# I-ONE therapy in patients undergoing total knee arthroplasty

<b>Submission date</b> 29/10/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 04/11/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/03/2013	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
001

## Study information

**Scientific Title**  
I-ONE therapy in patients undergoing total knee arthroplasty: Prospective and randomised study with a control group

**Acronym**  
IKA

**Study objectives**

Total knee arthroplasty (TKA) is often accompanied by a severe inflammatory reaction which, unless controlled, leads to persistent pain up to a year after surgery. Biophysical stimulation with I-ONE therapy has demonstrated to protect articular joint from catabolic activity of pro-inflammatory cytokines.

The aim of this study was to evaluate if patients undergoing TKA could benefit from I-ONE therapy, leading to early control of inflammation and relief of pain resulting in early and complete return to daily activities.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The local ethics committee of the General Hospital of Bari approved in December 2007

**Study design**

Prospective randomised controlled parallel group trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Knee arthritis

**Interventions**

Patients undergoing total knee arthroplasty will be randomised to receive either

1. I-ONE therapy, post-surgery, 4 hours/day for 60 days
2. Treatment as usual

The total duration of follow up will be 1 year

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Pain assessed by Visual Analogue Scale (VAS):

A 10 cm horizontal line corresponding to a scale evaluating the pain, where the left end stands for complete absence of pain and the right end the maximum possible pain or unbearable pain.

All outcomes will be assessed at 1, 2, 6 and 12 months.

**Key secondary outcome(s)**

1. Knee Society forms, involving a clinical evaluation, Knee Score (that assesses pain, range of motion, stability, contracture in bending, active extension deficit, alignment) and a functional one, Functional Score (that examines autonomy in walking, climbing stairs, use of stick or frame),

both with values from 0 to 100.

2. Functional evaluation scale SF-36, that 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: A scale, with scores from 1 to 40, to quantify 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 will be assessed at 1, 2, 6 and 12 months.

### **Completion date**

30/06/2010

## **Eligibility**

### **Key inclusion criteria**

1. Either sex, aged  $\geq 60$  and  $< 85$
2. Presenting an advanced state of knee arthritis and scheduled for prosthetic replacement
3. Misalignment in varus/valgus respectively not exceeding  $20^\circ$  and  $15^\circ$  and deformity in bending less than  $15^\circ$

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Senior

### **Sex**

All

### **Key exclusion criteria**

1. Patients who had undergone previous surgery to the same knee or had been operated on for hip prosthesis
2. Patients with BMI  $>30$  Kg/m<sup>2</sup>
3. Patients with pathological processes such as
  - 3.1. rheumatoid arthritis
  - 3.2. autoimmune conditions
  - 3.3. systemic diseases
  - 3.4. tumours

### **Date of first enrolment**

01/01/2008

### **Date of final enrolment**

30/06/2010

# Locations

## Countries of recruitment

Italy

## Study participating centre

Piazza Giulio Cesare, 11-Bari

Bari

Italy

70124

# Sponsor information

## Organisation

IGEA (Italy)

## ROR

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

# Funder(s)

## Funder type

University/education

## Funder Name

University of Bari (Italy)

## Funder Name

IGEA (Italy)

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	06/06/2012		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes