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I-ONE therapy in patients undergoing total knee arthroplasty

Submission date	Recruitment status	[_] Prospectively registered
29/10/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/11/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/03/2013	Musculoskeletal Diseases	

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

Primary study design
Interventional

Study design
Prospective randomised controlled parallel group trial

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 ≥ 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° and 15° and deformity in bending less than 15°

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/m2
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?
Results article	results	06/06/2012		Yes	No