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The Adler Genus Unicompartmental Knee Prosthesis post-marketing surveillance study

Submission date
25/02/2015

Recruitment status
No longer recruiting

Registration date
11/03/2015

Overall study status
Ongoing

Last Edited
21/08/2020

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Knee replacement surgery (arthroplasty) involves replacing a damaged, worn or diseased knee with an artificial joint (knee prosthesis). It is a routine operation for knee pain most commonly caused by arthritis. The aim of this study is to test the safety and effectiveness of the Genus Unicompartmental knee prosthesis over a period of 10 years.

Who can participate?
Patients aged 18-80 undergoing knee arthroplasty for osteoarthritis.

What does the study involve?
Participants will undergo knee replacement surgery using the Genus Unicompartmental knee prosthesis. They will be required to fill in yearly questionnaires concerning their knee and general wellbeing. They will also be required to attend clinical assessments after 1, 3, 5, 7 and 10 years, where a clinical assessment of the knee will be performed and an x-ray will be taken.

What are the possible benefits and risks of participating?
Possible benefits include prolonged clinical follow-up to assess the outcome of the operation over 10 years. Possible risks include exposure to additional radiation that is not part of normal practice; however, this has been assessed by a radiology expert and deemed to be of minimal risk.

Where is the study run from?
The Elective Orthopaedic Centre (EOC), in Epsom, Surrey, will be the study coordinating centre. Six further centres will participate in the clinical study.

When is the study starting and how long is it expected to run for?
From June 2014 to December 2027.

Who is funding the study?
Adler Ortho srl (Italy).

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

042C/2014/EOC/D5

Study information

Scientific Title
The clinical perfomances of the Genus Unicompartmental Knee Prosthesis manufactured by Adler Ortho srl will be evaluated by a multicentre prospective clinical surveillance study.

Study objectives
New Orthopaedic Implants introduced in the market should be followed in order to check their safety and efficacy. The aim of this study would be to assess safety (as defined by NICE and ODEP rating guidelines) and clinical performances of the Genus Unicompartmental knee over 10 years time on a cohort of 350 patients.

The Elective Orthopaedic Centre (EOC), in Epsom, Surrey, will be the study coordinating centre. Six further centres will participate in the clinical study, for seven total centres. Each participating centre will recruit approximately 50 patients. Patient recruitment will cease when a cohort of 350 Genus Unicompartmental knee prosthesis have been implanted.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Stanmore, 14/10/2014, ethics committee reference: 14/LO/1640, protocol number: 1/191113

Study design
Multicentre prospective clinical surveillance study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Osteoarthritis of the knee treated with knee arthroplasty (knee replacement surgery)

Interventions
Each patient will be submitted to the following set of investigation tools:
Pre-op: patient’s demographic and radiological review; baseline questionnaire - EuroQol, Oxford Knee and Knee Society scores.

Peri-op: operation details including peri-operative and early post-operative complications (complications that occur before patient discharge).
Post-op: Clinical Knee Society Score and radiological review at 1, 3, 5, 7 and 10 years and postal Oxford Knee and EuroQol scores annually.

X-rays will be checked looking for prosthesis alignment and any sign of loosening or wear.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Genus Unicompartmental knee prosthesis

Primary outcome measure
Implant survival rate keeping revision for any reason of any prosthetic component as an end point. Implant survival rate will be elaborated employing the Kapan-Meier statistical system.

Secondary outcome measures
1. Patients Oxford Knee score
2. Knee Society Score
3. EuroQol score
PROMs are being collected pre-op, 3 months, 6 months and annually after that. For clinical assessment it will be done at 1, 3, 5, 7 and 10 years post-operatively

Overall study start date
01/06/2014

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. A primary osteoarthritis of one compartment (medial or lateral)
2. Patients must be between the age of 18 and 80 at the time of consent
3. Listed for unicompartmental knee arthroplasty
4. Patients who are willing to give informed written consent
5. Absence of any degenerative disease of a progressive nature (e.g. rheumatoid arthritis)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
350 patients in total will be enrolled in the study. 7 centres will be in total involved, performing at least 50 implants each

Key exclusion criteria
1. Progressive local or systemic infection
2. Muscular loss, neuromuscular disease or vascular deficiency of the affected limb, making the operation unjustifiable
3. Severe instability secondary to advanced destruction of chondral structures or loss of integrity of the medial, lateral or either cruciate ligament
4. Any patient who cannot or will not provide informed consent for participation in the study
5. Those whose prospects for a recovery to independent mobility would be compromised by known coexistent medical problems
6. Patient whose BMI exceeds 45
7. Any case not described in the inclusion criteria

Date of first enrolment
22/01/2015

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
England

France

United Kingdom

Study participating centre
The Elective Orthopaedic Centre
Dorking Road
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Sponsor information

Organisation
Adler Ortho srl

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Adler Ortho srl (Italy)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The investigators expect to publish interim results as the study progresses.

Intention to publish date
31/12/2028

Individual participant data (IPD) sharing plan
Under the terms of their contract, the individual participant data will only be available to the healthcare professionals involved in the study and the study sponsor.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v2	14/10/2014	28/07/2020	No	No
HRA research summary			28/06/2023	No	No