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The treatment of medial compartmental knee osteoarthritis (OA) symptoms with the KineSpring™ Unicompartmental Knee Arthroplasty (UKA) System

Submission date
26/06/2009

Registration date
14/07/2009

Last Edited
12/09/2016

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
KINE-0902

Study information

Scientific Title
A multicentre open-label interventional study of patients with medial compartmental knee osteoarthritis (OA) symptoms treated with the KineSpring™ Unicompartmental Knee Arthroplasty (UKA) System

Acronym
COAST

Study objectives
The null hypothesis (H0) is that the Knee Society Score (KSS) for function derived from subjects treated with the KineSpring™ UKA System is inferior to a mean KSS for function of 80 which is widely reported in applicable literature:
H0: KSS less than or equal to 80 - d

The alternative hypothesis (H1) is that the KSS for function associated with KineSpring™ UKA System subjects is not inferior:
H1: KSS greater than 80 - d

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Ghent, Belgium, 07/10/2009
2. Leeds West Research Ethics Committee, UK, 21/10/2009
3. All other centers have received ethics approval before recruitment of the first participant

Study design

Prospective multicentre open-label non-randomised non-inferiority study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Osteoarthritis of the knee

Interventions
Arthroplasty of the knee. There is only one treatment arm as the results of this arm will be compared to a historical control. The surgical procedure lasts 1.5 to 2 hours. Enrolment will take place over 9 months with 24 year follow-up there after, so any one patient will participate in the study for a maximum of 24 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
The KSS Function score 6 months post-KineSpring™ UKA System surgery

Secondary outcome measures
1. Procedural success (i.e., successful implantation of the device)
2. Treatment-emergent AEs at surgery, 2 and 6 weeks, 3, 6, 12, 18, and 24 months (to include device malfunctions/unanticipated adverse device evaluations (UADEs)
3. Subject reported symptom severity changes from baseline measurement at 6 weeks, 3, 6, 12, 18, and 24 months in the following criteria:
3.1. KOOS score
3.2. EuroQol (EQ-5D)
3.3. Lysholm Knee Scale
3.4. Knee Specific Pain Scale
3.5. Investigator's assessment of patients' global status
3.6. Activity Profile
3.7. Patient Overall Treatment Evaluation
4. KSS knee and function scores at 6 weeks, 3, 6, 12, 18, and 24 months
5. KineSpring™ UKA System stability through evaluation of radiographic parameters at 3, 6, 12, and 24 month follow-up

Overall study start date

30/09/2009

Completion date
01/01/2014

Eligibility

Key inclusion criteria
1. Aged greater than or equal to 25 years, either sex
2. Diagnosis of medial OA of the target knee based on American College of Rheumatology (ACR) Clinical and Radiographic or Clinical Classification criteria for osteoarthritis with a minimum 12 month history
3. Continued knee pain despite minimum 3 months of conservative therapy, (i.e., physical therapy, bracing, orthotics, systemic or injected medications)
4. Knee flexion greater than or equal to 90 degrees
5. KSS knee and function scores less than 70
6. Weight greater than 60 kg
7. Ability to tolerate antibiotics
8. Willing and able to give voluntary written informed consent to participate in this clinical investigation
9. Prepared to consent to the transfer of his/her information to third parties
10. Willing to undertake the required investigational procedures and willing to return for the required follow-up evaluations

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Active infection, sepsis or osteomyelitis, history of infection in the target knee or distant foci of infections which may spread to the implant site
2. Rheumatoid arthritis or other forms of inflammatory joint disease
3. Significant OA in lateral or patellofemoral compartment
4. Previous surgery in the target knee within 12 months prior to screening
5. Previous osteotomy or failed knee endoprostheses of any kind in the target knee
6. Tibial-femoral varus or valgus alignment greater than 10 degrees
7. Ligamentous or meniscal instability as assessed by the Investigator
8. Concomitant immunosuppressive therapy
9. Paget's disease or metabolic disorders which may impair bone formation
10. Osteomalacia or moderate to severe osteoporosis, rapid joint destruction, marked bone loss or bone resorption noted on x-ray
11. Charcot's joint disease or other severe neurosensory deficits
12. Incomplete or deficient soft tissue surrounding the knee as assessed by the Investigator

13. Flexion deformity greater than 10 degrees
14. Uncontrolled diabetes mellitus or other significant co-morbidities
15. Any significant medical condition (e.g., significant psychiatric or neurological disorders, active alcohol/drug abuse, etc) or other factor (e.g. planned relocation, uncooperative patient) that the Investigator feels would interfere with study participation
16. The patient is pregnant or lactating
17. Historic or ongoing litigation for or participation in workers compensation for musculoskeletal injuries or disorders
18. Subjects who are currently enrolled in another clinical investigation

Date of first enrolment
30/09/2009

Date of final enrolment
01/01/2014

Locations

Countries of recruitment
Belgium

England

United Kingdom

Study participating centre
Robert Jones and Agnes Hunt Orthopaedic and District Hospital
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Sponsor information

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Moximed Inc. (USA)

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Sponsor type
Industry

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http://www.moximed.com/

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Funder(s)

Funder type
Industry

Funder Name
Moximed Inc. (USA)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration