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Clinical outcome and fusion rates after surgery with TM Ardis interbody fusion system

Submission date
19/12/2013

Recruitment status
No longer recruiting

Registration date
27/01/2014

Overall study status
Completed

Last Edited
14/04/2021

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

Background and study aims
Trabecular Metal™ is extensively used in many orthopaedic implants manufactured by the company Zimmer Spine (in hip replacements and knee replacements among other devices). Zimmer also has a wide range of Trabecular Metal™ spinal interbody fusion cages for the cervical as well as the lumbar spine. Manufactured entirely from Trabecular Metal™ material, the TM Ardis interbody device is intended for fusion at one or two connecting levels in the spine. This study is a post-market clinical follow-up study. The data collected from this study will serve the purpose of confirming the safety and performance of the TM Ardis implant.

Who can participate?
Patients suffering from degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis who have six months failed conservative treatment.

What does the study involve?
Over a period of two years participants will be followed on a regular basis (3,6, 12 and 24 months) to assess clinical outcomes and radiological parameters. Patients will be asked to answer some quality of life questionnaires as well as pain scales.

What are the possible benefits and risks of participating?
There will be no supplementary benefits than the one patients receive when having such a surgery.

Where is the study run from?
Six European centers will be involved in five countries (Spain, Germany, Sweden, Belgium, United Kingdom). For UK the hospital involved is Frimley Park NHS Foundation Trust.

When is the study starting and how long is it expected to run for?
There will be 1 year for recruitment and two years follow up. It is anticipated that recruitment in UK will begin by March 2014.

Who is funding the study?
Zimmer Spine (France)

Who is the main contact?
Dr Mark Thomas, FRCS in Frimley NHS Hospital

Contact information

Type(s)
Scientific

Contact name
Dr Mark Thomas

Contact details
Frimley Park NHS Foundation Trust
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02429908

Secondary identifying numbers
CME2013-01S

Study information

Scientific Title
A prospective, multi-center, post-market surveillance study to assess the clinical efficacy and fusion rates of the Zimmer®TM Ardis Interbody Fusion System

Acronym
TMARDIS

Study objectives
The goal of this study is to demonstrate that implant is effective in reducing patient disability, which will be assessed with the Oswestry Disability Index (ODI) questionnaire.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Regional Ethical Review Board in Gothenburg (Regionala etikprövningsnämnden i Göteborg), Sweden, 12/11/2013

2. Ethics Committee of the State Medical Association Brandenburg (Landesärztekammer Brandenburg), Germany, 07/08/2013
3. NHS Research Ethics Committees, UK - submission pending

Study design
Multi-center prospective open post-market surveillance study

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis

Interventions
Lumbar surgery: Over a period of two years participants will be followed on a regular basis (3, 6, 12 and 24 months) to assess clinical outcomes and radiological parameters. Patients will be asked to answer to quality of life questionnaires as well as pain scales.

Intervention Type
Device

Phase
Phase IV

Primary outcome measure
Improvement in patient's Oswestry Disability Index (ODI) score after TM Ardis cage insertion. A 15-point ODI improvement is expected to claim success of the criterion. Measure will be assessed preoperatively at 3, 6, 12 and 24 months.

Secondary outcome measures
The occurrence of implant-related complications defined as subsidence, breakage, migration and retrieval. Except radiological tests, the outcomes will be measured with questionnaires in native language preoperatively at 3, 6, 12 and 24 months. Radiological parameters calculation will be assessed by an external company.

Overall study start date
03/03/2014

Completion date

31/05/2018

Eligibility

Key inclusion criteria
1. Age 18 years or over
2. Degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.
3. ODI over or equal to 40/100
4. Back pain over or equal to 4/10
5. Mono segmental lumbosacral disease fulfilling the prior conditions: only one level between L2 and S1
6. Skeletally mature patients
7. Six months failed conservative treatment
8. Gave written consent to take part in the study by signing patient informed consent form
9. Physically and mentally able to comply with the protocol, including ability to read and complete required forms and adhere to the follow-up requirements of the protocol

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80 in total

Key exclusion criteria
1. Prior surgical procedure at the index level using the desired operative approach
2. Severe degenerative lesions at more than one level of the lumbosacral spine
3. Morbid obesity (BMI ≥ 40)
4. Active local infection in or near the operative region
5. Active systemic infection and/or disease
6. Severe osteoporosis or insufficient bone density, which in the medical opinion of the physician precludes surgery or contraindicates instrumentation
7. Known or suspected sensitivity to the implant materials
8. Endocrine or metabolic disorders known to affect osteogenesis (e.g. Paget's disease, renal osteodystrophy, hypothyroidism)
9. Systemic disease that requires the chronic administration of nonsteroidal anti-inflammatory or steroidal drugs
10. Significant mental disorder or condition that could compromise the patient's ability to remember and comply with preoperative and postoperative instructions (e.g. current treatment for a psychiatric/psychosocial disorder, senile dementia, Alzheimer's disease, traumatic head injury)

11. Neuromuscular disorder that would engender unacceptable risk of instability, implant fixation failure, or complications in postoperative care
12. Pregnant
13. Unwilling to follow postoperative instructions, in particular with respect to athletic or occupational activities
14. Current vertebral metastatic tumors
15. Symptomatic cardiac disease
16. Severe congenital or acquired vertebral deformities

Date of first enrolment
03/03/2014

Date of final enrolment
29/10/2015

Locations

Countries of recruitment
Belgium

England

Germany

Spain

Sweden

United Kingdom

Study participating centre
Frimley Park NHS Foundation Trust
Frimley
United Kingdom
GU167UJ

Sponsor information

Organisation
Zimmer Spine (France)

Sponsor details
23 Parvis des Chartrons
Bordeaux Cedex
France
33080

Sponsor type
Industry

ROR
https://ror.org/029j6tp05

Funder(s)

Funder type
Industry

Funder Name
Zimmer Spine (France)

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