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Osigraft Study: a prospective, randomised, controlled, multicentre, (pilot) study of Osigraft® in instrumented posterolateral fusions

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
31/03/2015

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
EU 101; NTR217

Study information

Scientific Title
Osigraft Study: a prospective, randomised, controlled, multicentre, (pilot) study of Osigraft® in instrumented posterolateral fusions

Study objectives
It is postulated that the use of Osigraft® will prove beneficial in the treatment of patients requiring decompression and instrumented lumbar spinal fusion while eliminating the pain and morbidity associated with harvesting of autograft bone from the iliac crest.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Multicentre randomised double-blinded active-controlled parallel-group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Degenerative disc disease (DDD), spondylolisthesis

Interventions
All subjects will receive decompression and posterolateral spinal fusion via instrumented pedicle fixation. There will be two arms: a treatment arm with Osigraft® and local autograft and a control arm using autogenous bone graft from the iliac crest.

Intervention Type
Procedure/Surgery

Primary outcome(s)
In order for a patient to be classified as a success, the patients has to meet all of the criteria mentioned below:
1. Radiographic demonstration of spinal fusion
2. Oswestry Disability Index improvement of at least 20% from the pre-treatment visit
3. No revisions, removals or supplemental fixations may occur
4. Absence of a serious investigational-product -related adverse event during the course of the study
5. No unresolved neurological deficits at the final examination that were not present prior to study treatment
6. No decreases in neurological status at the final examination from the preoperative evaluation

Key secondary outcome(s))

Not provided at time of registration

Completion date
16/10/2006

Eligibility

Key inclusion criteria
1. Diagnosis of degenerative and/or isthmic spondylolisthesis and/or degenerative disc disease (DDD) at the levels of L3-S1 with:
1.1. Lumbar instability of at least 2 to 3 mm translation in standing standard radiographs, or
1.2. At least 2 to 3 mm translation in flexion extension radiograms and/or angulation motion defined as greater than 15° at L3-L4 level, greater than 18° at L4-L5 level, and greater than 17° at L5-S1 spine level
2. Leg and/or back pain with one or more of the following phenomena: radiculopathy, sensory deficit, motor weakness, reflex pathology, neurogenic claudication
3. The subject has been non-responsive to at least 6 months of non-operative treatment prior to study enrolment
4. The subject has a preoperative Oswestry Disability Index of 30 - 100
5. Fusion of only one lumbar level in the L-3 to S-1 region is indicated
6. The subject has no history of previous fusion attempt(s) to the affected spinal level
7. The subject is willing and able to understand, sign and date the study specific patient informed consent, which has been approved by the Institutional Review Board
8. The subject agrees to comply with post-operative clinical and radiographic evaluations and required rehabilitation regimen
9. Age: the subject is skeletally mature between 18 and 80 years of age
10. Gender: both males and females can be included in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. The subject has gross instability as a result of degenerative and/or isthmic spondylolisthesis and/or DDD that requires multiple levels fusion (an example would be exclusion of grade IV spondylolisthesis)
2. The subject is severely osteoporotic/osteopenic as manifested by the presence of a history of osteoporotic spine fractures and/or medical treatment for osteoporosis and/or such changes on the AP/lateral radiographs that will make the surgeon decide to exclude this patient from any

form of pedicle fixation
3. The subject has an active spinal and/or systemic infection
4. The subject has a systemic disease or condition, which would affect his/her ability to participate in the study requirements or the ability to evaluate the efficacy of the investigational product (i.e. active malignancy, neuropathy)
5. The subject is a prisoner, a transient or has been treated for alcohol and/or drug abuse in an inpatient substance abuse program within six months prior to proposed study enrolment
6. The subject has participated in clinical trials evaluating investigational devices, pharmaceuticals or biologics within 3 months of enrolment in the study
7. The subject is a woman who intends to bear children within 1 year of enrolling in the study (e. g. is not post-menopausal, has not had a hysterectomy, is not on long term oral contraception)
8. The subject is morbidly obese (defined as weight greater than 60 percent over the recommended ideal weight as described in the 1996 Metropolitan Height and Weight Tables for Men and Women, Appendix B)
9. The subject has a known sensitivity to any component of Osigraft®
10. The subject is known to require at the time of treatment, additional surgery to the lumbar spinal region within the next six months
11. Patients who have in the last year been prescribed systemic corticosteroids

Date of first enrolment
14/07/2004

Date of final enrolment
16/10/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Center Utrecht
Utrecht
Netherlands
3508 GA

Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (Netherlands)

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Industry

Funder Name
Stryker Nederland BV (The Netherlands)

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	19/08/2013		Yes	No