Osigraft Study.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19983

Bron
NTR

Verkorte titel
N/A

Aandoening

Degenerative and/or Isthmic Spondylolisthesis and/or Degenerative Disc Disease (DDD) at the levels of L3-S1, requiring one-level instrumented posterolateral fusion with pedicular fixation.

Ondersteuning

Primaire sponsor: Department of Orthopaedics
University Medical Center Utrecht
The Netherlands
Overige ondersteuning: Styker Biotech
University Medical Center Utrecht

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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-produc -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.

Toelichting onderzoek

Achtergrond van het onderzoek

Instrumented posterolateral fusion of the lumbar spine is a commonly performed procedure for a variety of spinal disorders. The classical technique for achieving spinal fusion involves placing autologous bone graft between the spinal surfaces.The bone graft stimulates new bone formation. However, harvesting of bone from the posterior iliac crest is associated with significant complications.

Osigraft contains rhBMP-7 and has shown to be capable of bone formations. The purpose of the study is to establish Osigraft® as a safe alternative to autograft for instrumented posterolateral fusion of the lumbar spine and thereby avoiding the pain and morbidity associated with iliac crest bone harvesting.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1.Diagnosis of Degenerative and/or Isthmic Spondylolisthesis and/or Degenerative Disc Disease (DDD) at the levels of L3-S1 with;

a. Lumbar instability of at least 2 to 3 mm translation in standing standard radiographs;

b. at least 2 to 3 mm translation in flexion extension radiograms29,30 and/or angulation motion defined as >15° at L3-L4 level, >18° at L4-L5 level, and >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 enrollment;

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 enrollment;

6. The subject has participated in clinical trials evaluating investigational devices, pharmaceuticals or biologics within 3 months of enrollment 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 >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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	14-07-2004
Aantal proefpersonen:	150
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	05-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL180
NTR-old	NTR217
Ander register	: EU 101
ISRCTN	ISRCTN43648350

Resultaten

Samenvatting resultaten
N/A