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Study on cervical resorbable interbody cages

Submission date	Recruitment status	[ ] Prospectively registered
22/02/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/04/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/01/2017	Musculoskeletal Diseases	[ ] 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
SLCRG2007001

Study information

Scientific Title

Solis (polyaryletheretherketone [PEEK]) versus Solis (poly-L-lactic acid [PLLA]) resorbable cage for anterior cervical discectomy with fusion: controlled randomised clinical outcomes study

Acronym
CLEAR

Study objectives
Anterior cervical disc excision followed by interbody arthrodesis is a standard surgical procedure to treat patients with symptomatic cervical spondylosis. Resorbable materials have recently been introduced in spinal surgery. The advantage of these materials is that they offer the correct mechanical environment to achieve fusion, but are absorbed over time, therefore avoiding long term adverse events. The extent of this improvement needs to be assessed objectively and compared to current standard care.

Disease information:
Single level degenerative disc disease of the cervical spine at a level between C3-C4 and C6-C7 with symptomatic myelopathy and/or radiculopathy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. Netherlands: VUmc METC, 17/08/2007, ref: 2007/58
2. Germany: Ethik-Kommission der Bayerischen Landesärztekammer, 19/06/2007, ref: 07036
3. Denmark: Den Videnskabsetiske Komité for region Syddanmark, 07/07/2007, ref: S-20070049
4. France: CPP Est-II CHU Hôpital St Jacques, 10/09/2007, ref: 07/451
5. Spain: Comité Ético de Investigación Clínica del Hospital Universitario de la Princesa, 15/10 /2007, ref: 1189

Ethics approval pending as of 22/02/2008 from:
United Kingdom: Leeds (West) Research Ethics Committee, ref: 07/H1307/192

Study design
Multi-centre European prospective randomised controlled single-blinded outcome study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

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
Degenerative disc disease of the cervical spine

Interventions
Anterior cervical discectomy with fusion:
Group 1: Anterior single level cervical discectomy procedure with a Solis (non-resorbable PEEK) interbody cage device (no internal fixation)
Group 2: Anterior single level cervical discectomy procedure with a Solis RS (bioresorbable PLLA) interbody cage device (no internal fixation)

The follow-up time is two years for each patient.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Acquired fusion at six months
2. Subsidence and dynamic behaviour at every follow up
3. Absorption rate (for Solis RS only) at 24 months

Secondary outcome measures
1. Visual Analogue Scale (VAS) score for arm and neck pain at every follow up (3, 6, 12, 24 months)
2. Neck Disability Index (NDI) at every follow up
3. Myelopathy Disability Index (MDI) at every follow up
4. Prolo Economic and Functional Scale at every follow up

Overall study start date
01/08/2007

Completion date
31/12/2010

Eligibility

Key inclusion criteria
1. Willing and able to participate
2. Patient is male or female and between 18 and 70 years of age
3. Patient has clinical symptomatic myelopathy and/or radiculopathy
4. Based on clinical history, physical examination and radiographic evidence, pain interpreted as emanating between C3/4 and C6/7
5. No improvement of symptoms after at least three months of conservative treatment
6. Progressive neurological deficit despite conservative management irrespective of the duration
7. Evidence of degenerative changes between levels C3/4 and C6/7 (spondylosis) as shown on plain radiographs and/or computed tomography (CT) scan and/or magnetic resonance imaging (MRI). The pathology should be predominant on one level. Other levels may show degeneration, however, it should not be clinically necessary to operate on.
8. Use of autograft from the iliac crest or the spine is necessary
9. Capable of providing informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
113

Key exclusion criteria
1. Previous cervical spine surgery at the symptomatic level to be operated on and previous cervical spine surgery during the last two years at other levels
2. Symptomatic degenerative disc disorder at more than one cervical level
3. Pregnancy or planning a pregnancy during the two year study
4. Ongoing severe psychiatric illness or mental retardation
5. Evidence of alcohol and/or drug abuse
6. Inability to complete the questionnaires
7. Local or general infection which could jeopardise the surgical objective
8. Extensive local inflammatory reactions
9. Proven or suspected hypersensitivity to materials
10. Immunosuppressive pathologies
11. Abnormal, immature or weak bone structure, insufficient quantity or quality or diseased bone that is incapable of supporting or stabilising the device
12. Severe pathologies of the airway, oesophagus, abnormal vascostructure or bypassing nerves
13. Other indications than degenerative spinal disorders including a metabolic bone disease, osteoporosis, infection, previous cervical spinal fracture, inflammatory process or neoplasm (confirmed by radiographs and/or dual energy x-ray absorptiometry [DEXA] scans and/or CT and /or MRI)
14. Excessive physical activity

Date of first enrolment
01/08/2007

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Denmark

France

Germany

Netherlands

Spain

United Kingdom

Study participating centre
VU University Medical Center
Amsterdam
Netherlands
1081 HV

Sponsor information

Organisation
Stryker SA (Switzerland)

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Sponsor type
Industry

Website
http://www.europe.stryker.com/

ROR
https://ror.org/04t7jet59

Funder(s)

Funder type
Industry

Funder Name

Stryker SA (Switzerland)

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