

# Study on cervical resorbable interbody cages

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<b>Registration date</b> 03/04/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 05/01/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**Protocol serial number**  
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 Videnskabetiske 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

## **Study type(s)**

Treatment

## **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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

United Kingdom

Denmark

France

Germany

Netherlands

Spain

**Study participating centre**

**VU University Medical Center**

Amsterdam

Netherlands

1081 HV

## **Sponsor information**

**Organisation**

Stryker SA (Switzerland)

**ROR**

<https://ror.org/04t7jet59>

**Funder(s)****Funder type**

Industry

**Funder Name**

Stryker SA (Switzerland)

**Results and Publications****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration