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Safety and effectiveness of TOPS™ System

Submission date 23/07/2013	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 02/08/2013	**Overall study status** Completed	
Last Edited 27/02/2018	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Degenerative spondylolisthesis is a condition where abnormal and excessive movement of the bones in the spine (vertebrae) causes pain in the lower back and legs. Spinal stenosis is a condition where compression of the nerves in the spine causes pain, numbness and tingling in the legs. When non-surgical treatment of these conditions is not effective, pain relief is typically achieved with surgery to fuse the affected vertebrae. While fusion may decrease the pain generated at the treated vertebrae, it increases the load on the adjacent vertebrae, causing a condition which may require further surgery in the future. The TOPS™ System is a mechanical device that effectively replaces the structures that are removed from the vertebrae during surgery. It is an alternative to spinal fusion that is designed to stabilize but not fuse the affected vertebrae, protecting against the problems associated with fusion. The aim of this study is to establish the safety and effectiveness of the TOPS™ System and provide evidence that the TOPS system provides better clinical outcomes than fusion.

Who can participate?
Patients aged 40-85 with lower back and leg pain resulting from spinal stenosis and/or degenerative spondylolisthesis.

What does the study involve?
Participants undergo spinal surgery with the TOPS™ System and are followed up for 2 years. They complete questionnaires to evaluate pain-related issues, wellbeing and quality of life, and have a series of x-ray images taken to evaluate the function and performance of the TOPS™ System.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Southampton Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2013 to November 2015

Who is funding the study?
Premia Spine Ltd (Israel)

Who is the main contact?
John Fowler

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1513-CL-VL-01 SOU UK

Study information

Scientific Title
A study to evaluate the safety and effectiveness of TOPS™ System: a non-randomized single centre study

Study objectives
The purpose of this prospective clinical study is to establish the safety and effectiveness of the TOPS™ System used following decompression, in the treatment of lower back and sciatic pain with, or without spinal claudication, that results from degenerative spondylolisthesis or spinal stenosis at one vertebral level between L3 and L5, with or without concomitant adjacent segment disease that requires a lumbar fusion.

Ethics approval required
Old ethics approval format

Ethics approval(s)

University Hospital Southampton NHS Foundation Trust, 24/02/2014, ref: RHM T&O0155

Study design
Non-randomized single-centre study

Primary study design
Interventional

Secondary study design
Non randomised study

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
Single Level Lumbar Spine Stenosis (with up to a grade 1 spondylolisthesis)

Interventions
This study will involve patients having surgery for their back/leg pain as per the standard of care currently offered to them.
Patients will be followed up for a period of 2 years post-operation. They will be questioned using standard ODI, VAS and ZCQ to evaluate pain related issues and well being / quality of life etc. They will also have a series of radiographic images taken, again to evaluate the resultant function of the TOPS and monitor its performance in line with current clinical evidence.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
1. Individual Patient Success
2. Pain/Function/Disability at 24-month evaluation: Subjects who exhibit a reduction of 15 percent in their Oswestry Low Back Pain Disability Questionnaire score compared to their preoperative Oswestry score will be considered a success. Beurkens et al. has reported a change of 4 to 6 points of the 100 points for the Oswestry to represent a clinically significant improvement
3. Subjects who exhibit a reduction of 20mm in their VAS Leg Score (combined leg score)
4. Radiographic: Any TOPS subject will be considered a failure if fusion occurs as defined in the radiographic protocol

Secondary outcome measures

Although the main goal of this trial is to address the primary endpoint of overall effectiveness at 24 months, individual outcome endpoints will be evaluated and will include average improvement in back and leg visual analog scales (VAS), ZCQ scores, quality of life (SF-36), and maintenance or improvement in neurological symptoms. When possible, other factors such as vertebral range of motion, disc height, length of stay, OR time, blood loss, work status pre-surgery, return to work status, time to recovery and narcotic use will be evaluated. An economic analysis of patient and hospital costs for each study group may also be performed.

Overall study start date
01/10/2013

Completion date
30/11/2015

Eligibility

Key inclusion criteria
The study population will be comprised of patients suffering from lower back and leg pain which results from degenerative spondylolisthesis and/or spinal stenosis who meet the eligibility criteria as follows
1. Patients with one or both of the following conditions at a single spinal level between L3 and L5 are eligible for the TOPS™ System implant:
1.1. Symptomatic monosegmental lumbar spinal stenosis
1.2. Degenerative Spondylolisthesis up to and including grade 1 (see radiographic protocol)
2. Patients with one or more of the following conditions at one or two levels adjacent to the TOPS System between L4 and S1 are eligible for the Versalink™ Fixation System implant:
2.1. Symptomatic monosegmental lumbar spinal stenosis
2.2. Degenerative Spondylolisthesis up to and including grade 1 (see radiographic protocol)
2.3. Discogenic pathology
3. At least three (3) months of failed, conservative treatment prior to surgery, including use of anti-inflammatory medications at maximum specified dosage; administration of epidural/facet injections, unless deemed inadvisable due to progressive motor weakness or other evidence of rapidly deteriorating condition; rest, heat, electrotherapy/physical therapy
4. Narrowing of the lumbar spinal canal classified as moderate to severe using CT scans/MRI
5. Age 40-85 years old (male or female)
6. Lower back pain and sciatica with or without spinal claudication
7. Psychosocially, mentally and physically able to fully comply with the clinical protocol and willing to adhere to follow-up schedule and requirements.
8. Leg pain of at least 40/100 at baseline as per visual analogue scale (VAS)
9. Oswestry Questionnaire score of at least 40/100 at baseline

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
10

Key exclusion criteria
Patients who have any of the following conditions or meet any of the following criteria are excluded from participating in this study:
1. Primary diagnosis of discogenic back pain at the TOPS System level
2. Back or non-radicular leg pain of unknown etiology at the TOPS System level
3. Lytic spondylolisthesis at the TOPS System level
4. More than one (1) motion segment involved in the degenerative pathology to the extent that justifies its inclusion in the surgical procedure, unless a decompression alone can be done at that level without compromising stability or the Versalink System is implanted.
5. Known allergy to titanium and/or polyurethane
6. Prior surgery at any lumbar vertebral level
7. Supplemental interbody support required (e.g., bone graft, spacers, VBRs, or fusion cages) at the TOPS System level
8. Clinically compromised vertebral bodies at the affected level(s) due to any traumatic, neoplastic, metabolic or infectious pathology.
9. Deformity of the spine that would compromise the implant, e.g. scoliosis of greater than ten (10) degrees
10. Morbid obesity defined as a body mass index > 40 or a weight more than 100 lbs. over ideal body weight
11. DEXA bone density measured T score equal to or lower than 2.0
12. Paget's disease, osteomalacia, osteogenesis imperfecta, thyroid and/or parathyroid gland disorder and/or any other metabolic bone disease
13. Active infection - systemic or local
14. AIDS, HIV, or active hepatitis
15. Rheumatoid arthritis or other autoimmune disease
16. Tuberculosis active or in the past 3 years
17. Active malignancy: A patient with a history of any invasive malignancy (except non-melanoma skin cancer), unless he/she has been treated with curative intent and there have been no clinical signs or symptoms of the malignancy for at least 5 years
18. Medical conditions requiring treatment with any drugs known to potentially interfere with bone/soft tissue healing
19. Pregnant or interested in becoming pregnant in the next 3 years
20. Current chemical/alcohol dependency or significant psychosocial disturbance
21. Subject is currently involved in another investigational study
22. Cauda equina syndrome or neurogenic bowel/bladder dysfunction
23. Severe arterial insufficiency of the legs, peripheral vascular disease
24. Sustained pathologic fractures of the vertebra or multiple fractures of the vertebra or hip
25. Unremitting pain in any spinal position
26. Significant peripheral neuropathy
27. Immunologically suppressed, received steroids > 1 month out of the past year
28. Insulin-dependent diabetes mellitus
29. Currently taking anticoagulants other than aspirin (e.g., Plavix)
30. Life expectancy less than 3 years
31. Waddell signs > 3
32. Currently involved in active spinal litigation
33. Subject is incarcerated

Date of first enrolment

01/10/2013

Date of final enrolment
30/11/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Southampton Hospital
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Sponsor information

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Premia Spine Ltd (Israel)

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Premia Spine Ltd (1513-CL-VL-01 SOU UK) (Israel)

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