A pilot study to evaluate the Safety and Performance of the Percutaneuos Dynamic Stabilization (PDS) system for the treatment of mild to Moderate Degenerative Disc disease

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Primary Objective The primary objective of this study is to evaluate the clinical performance of the PDS System as measured by the Oswestry Disability Index. Specifically, the percent reduction at 6 months relative to pre-treatment will constitute...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON30202

Source
ToetsingOnline

Brief title
PDS stabilization

Condition

- Bone and joint therapeutic procedures

Synonym
Degenarative diseases

Research involving
Human

Sponsors and support

Primary sponsor: mediqol
Source(s) of monetary or material Support: Triage

Intervention

Keyword: Mild to Moderate, Percutaneous Dynamic Stabilization, Pilot study, Safety and Performance

Outcome measures

Primary outcome

The primary endpoint, percent reduction in the Oswestry Disability Score (at

six months relative to pre-treatment), will be analysed using both a paired

t-test and the non-parametric Wi1coxon signed¬rank test.

Secondary outcome

All secondary endpoints (see Section 3.4) will be analysed using appropriate

descriptive statistical techniques and where possible, paired or repeated

measures statistical analyses will be conducted in order to examine the

Oswestry Disability Index, the SF-36, the Visual Analogue Scale, and patient

satisfaction over time (baseline, 6 weeks, 3 months, 12 months).

Study description

Background summary

Degenerative disc disease (DDD) affects approximately 40 to 50% of people over the age of 40 and is a part of the natural process of growing older. Unfortunately as part of this process, the intervertebral discs lose their flexibility, elasticity and shock absorbing characteristics which can result in a loss of disc height. Disc height is important as it separates the vertebra above from the one below. When disc height is lost the nerve root pathways may become narrowed and cause nerve impingement, resulting in inflammation and pain. Patients often report their symptoms as ranging from mild occasional

backaches to chronic low back pain that is severe enough to limit their activities at work and leisure. The pain is typically mechanical in nature (Modic MT, 1999).
Current treatments for DDD may include a period of conservative treatment including pain management programmes, physiotherapy and possibly injection therapy. Conservative treatment may not always reduce pain and improve function and surgical options may need to be considered. Surgery for degenerative lumbar lesions is undergoing a .transforrllation with the current emergence of the step-wise surgical strategy concept to treat chronic lumbar pain when conservative treatment fails.
While spinal fusions may be the gold standard treatment for patients suffering from low back pain due to DDD, there is significant clinical interest in developing technologies that would alleviate the pain while maintaining the spine's natural biomechanics. One. such concept is dynamic stabilization (Christie SD et al., 2005). Dynamic stabilization can be used on patients that have failed conservative treatment but do not want to hav~ fusion. Typically, dynamic stabilization devices are "reversible" in the sense that they can be removed and additional surgery, such as fusion, can be performed at a later date.
Dynamic stabilization has been defined as "a system that would alter favourably the movement and load transmission of a spinal motion segment, without the intention of fusing of the segment." In other words, such a system would restrict motion in the direction or. plane that produces pain, or painful motion, but would otherwise allow a full range of motion.

Study objective

Primary Objective
The primary objective of this study is to evaluate the clinical performance of the PDS System as measured by the Oswestry Disability Index. Specifically, the percent reduction at 6 months relative to pre-treatment will constitute the primary endpoint of the pilot study.

Secondary Objectives
The secondary objectives of this study are to further evaluate the clinical performance and the safety of the PDS System.

Study design

This will be a pilot study to evaluate the safety and clinical performance of the PDS System in subjects who have mild to moderate disc degenerative disease. All patients who are considered eligible to participate in the study and give consent will 'receive the PDS System. The recruitment period is estimated as 8 months with anticipated duration of 20 months.
Patients included in the study will be evaluated at screening, on hospital admission prior to treatment, at treatment, at discharge and at 6 weeks, 3, 6

and 12 months post-treatment. A study flow chart is presented in Appendix I.

Intervention

NA All interventies are standard conform the hospital protocol for this sort of patients.

Study burden and risks

NA

Contacts

Public
mediqol

basdongenstraat 25 C
3120
belgie
Scientific
mediqol

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3120
belgie

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

•Patients aged between 18 and 60 years of age inclusive.
•Patients with evidence of mild to moderate degenerative disc disease at a single level of the lumbar spine (L 1 through to SI) confirmed by MRI within the last 6 months.
•Patients with clinical evidence of degenerative disc disease experiencing back pain and confirmed by provocative discography at the target level.
•Patients who have failed to adequately improve following a 3 month period of conservative management, who in the opinion of the Clinical Investigator, require surgical intervention or aggressive conservative management.
•Patients who have a minimum baseline Oswestry Score of30% (15/50).
•Patients who are able to give voluntary, \vritten informed consent to participate in this study and from whom consent has been obtained.
•Patients, who, in the opinion of the Clinical Investigator, are able to understand this study, co-operate with the procedures and are willing to return to the hospital for all the required post-operatiw follOw'-up procedures.

Exclusion criteria

•Patients who, in the opinion of the Clinical Investigator, haw 2.would compromise their participation and follow-up in this study.
•Patients who have rheumatoid arthritis, lupus, osteoporosis (T<1.0) disease, osteomalacia, Paget's disease, other metabolic bone disease : syndrome.
•Patients who have significant spondylosis, scoliosis, kyphosis or any oc~-condition which would compromise their participation.
•Patients with evidence of tumour and/or malignant disease with resultant life expectancy of less than one year.
•Patients who are immunocompromised or being treated with immunosuppressive agents. and/or present with a significant general illness that decreases the probability of surviyal.
•Patients who have leg pain without back pain ..
•Patients with greater than 50% disc collapse as compared to adjacent discs.
•Patients with Modic 2 or Modic 3 bone changes at the target level.
•Patients with radiographic confirmation of severe facet joint disease or degeneration.
•Patients with clinically compromised vertebral bodies at the affected level due to current or past trauma like sustained pathological fracture or multiple fractures of vertebrae.
•Patients with evidence of an active systemic infection or an infection at the target level.
•Patients with a known allergy to titanium and/or polycarbonate urethane (PCD).
•Subjects with concomitant conditions requiring steroid treatment or prior steroid usage within the last 3 months.
•Patients who have previously had spine surgery performed at the target level or an adjacent level.
•Patients who have previously participated in any experimental spinal implant or treatment.
•Patients who have any injury litigation claims pending.
•Patients who are known drug or alcohol abusers or with psychological disorders that could

affect follow-up care or treatment outcomes.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-07-2007
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	12-12-2006
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL15056.075.06