A MultiCenter Prospective Randomized Phase II Clinical Trial to Evaluate Safety and Efficacy of Hyalospine® in Lumbar Laminectomy or Laminotomy.

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Primary objectives of the study are (i) to evaluate short*term safety of HYALOSPINE and (ii) to evaluate efficacy of HYALOSPINE in prevention of adhesions and fibrosis following single* or two*level lumbar laminectomy or laminotomy in patients with...

Ethical review	Approved WMO
Status	Pending
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON32769

Source
ToetsingOnline

Brief title
Efficacy and safety of Hyalospine®

Condition

- Joint disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
spinal stenosis or disc herniation

Research involving
Human

Sponsors and support

Primary sponsor: Fidia Advanced Biopolymers (FAB) S.r.l.
Source(s) of monetary or material Support: Fidia Advanced Biopolymers

Intervention

Keyword: Epidural fibrosis, Laminectomy, Laminotomy, Spinal stenosis

Outcome measures

Primary outcome

Safety: Frequency and severity of adverse events (AE) (including surgical complications). All AE will be monitored and evaluated continuously. Comparisons of AE between the interventional and control group will be made at 6 and 12 month follow-ups. Additional comparisons at any point considered as necessary by the Safety Officer.

Primary variables

Efficacy: Extent of epidural fibrosis and adhesions as measured on MRI after 6 and 12 month follow*up.

Secondary outcome

Secondary variables

• Patient Reported Outcomes:

o Oswestry Disability Index (ODI) v2.1

o Pain at back/buttocks (NRS)

o Pain at legs (NRS)

o SF-36v2.0

o EQ-5D

o Zurich Claudication Questionnaire (ZCQ)

• Neurological status.

• Blood loss, surgery time, use of cell savers,

• Changes in clinical laboratory hematologic evaluations.

• Immunologic response.

Study description

Background summary

Extensive epidural scar adhesions, referred as laminectomy membrane, often occur in the laminectomy defect after spine surgery and can have a role in unfavourable patient outcome. Formation of dense and thick scar tissue which adheres to the surgically exposed dura mater and adjacent nerve roots can result in extradural compression or dura tethering, causing recurrent radicular pain and physical impairment. Patients who presented with extensive epidural scarring at the MRI evaluation were more likely to suffer from recurrent pain compared to patients without signs of extensive scars.
Hyalospine is an implantable device, in form of aqueos gel, to be used as a mechanical barrier to prevent or decrease post*surgical adhesions.

Study objective

Primary objectives of the study are (i) to evaluate short*term safety of HYALOSPINE and (ii) to evaluate efficacy of HYALOSPINE in prevention of adhesions and fibrosis following single* or two*level lumbar laminectomy or laminotomy in patients with lumbar stenosis or disk herniation.

Secondary objectives are to evaluate differences in pain, neurological status, function, quality of life outcomes, clinical hematologic laboratory changes, and immunologic response between the investigational and control groups.

Study design

This study is a prospective randomized double (patient and evaluator) blinded controlled trial. Patients will be randomized to one of the treatment arms in a ratio of 1:1. Outcomes will be evaluated at 3 weeks ± 1 weeks, 6 weeks ± 2 weeks, 6 months ± 1 month, 12 months ± 2 months, and at all unplanned visits.

The randomization will occur at the time when the main surgery has been

completed and after the intraoperative exclusion critera have been verified. Patients who do not meet the intraoperative criteria are not randomised and excluded from the study. Such patients will not count towards the study sample size.

Intervention

Hyalospine is a medical device in form of a gel with a final concentration of 30 mg/ml constituted by 18 mg of gellan and 11 mg of HA-S, in 0.9% saline solution. Hyalospine is an implantable device, in form of aqueos gel, to be used as a mechanical barrier to prevent or decrease post-surgical adhesions. The product is presented in glass 2.5 ml syringes and the packaging includes a suitable canula to help in spinal canal administration.

Study burden and risks

The patient will visit the hospital 6 times during the study. During each visit questionnaires will be administered and a blood sample will be drawn. At 6 and 12 months an MRI with contrast fluid will be taken. Risks are asociated with MRI with contrast (headache, allergy), medical device and the general risks associated with spinal surgery. Benefit of te device is anticipated as less adhesions and fibrosis at the operative site.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Age 18 * 75 years;
• Scheduled for elective single or two*level lumbar laminectomy or laminotomy procedure for treatment of spinal stenosis or disk herniation.
• Subjects who have failed conservative care for at least 6 weeks.
• At least 25% narrowing of the central, lateral or foraminal spinal canal compared to the adjacent levels.
• Radiographic confirmation of any one of the following:
o Evidence of the tecal sac and/or cauda equina compression
o Evidence of nerve root impingement (displacement or compression) by either osseous or non*osseous elements
o Evidence of hypertrophic facets with canal encroachment
• Skeletally mature.
• Able to understand this clinical study and willing and able to participate in the study follow*up according to the protocol.
• Understand and read country national language at elementary level.
• Signed informed consent.
• Women must be one of the following:
o Postmenopausal defined as amenorrhea for at least 6 months before screening and a serum follicle stimulating hormone (FSH) level consistent with postmenopausal status
o Surgically sterile, (have had a hysterectomy or bilateral oophorectomy, tubal ligation, or otherwise be incapable of pregnancy)
o Abstinent (at the discretion of the investigator) or,
o If sexually active, be practicing an effective method of birth control such as hormonal prescription oral contraceptives, progesterone implants or injections, intrauterine device (IUD), a double*barrier method such as condoms, diaphragms or cervical caps with spermicidal foam, cream or gel, or male partner with a vasectomy.
• Women of childbearing potential must have a negative serum β*human chorionic gonadotropin (β*hCG) pregnancy test at screening, or a negative urine pregnancy test at baseline or screening.

Exclusion criteria

• Systemic infection such as AIDS, HIV, and active hepatitis.
• Systemic Lupus erythematosus.
• Contraindication to MRI (e.g. any electrically, magnetically or mechanically activated implants).
• Known allergic reaction to MRI contrast.
• Instrumented fusion (Exception: non*instrumented fusion permissible).
• Postoperative wound treatment planned with suction drainage device (Exception: treatment with gravity drainage device allowed).
• Patient has post traumatic vertebral body compromise or fracture at surgery level.
• Prior lumbar spine surgery at surgery level.
• Undergoing treatment for tumor or bony traumatic injury to the lumbar spine.
• Cauda equina syndrome (defined as neural compression causing neurogenic bowel or bladder dysfunction).
• Significant symptomatic peripheral vascular disease (at the discretion of the investigator).
• Active malignancy defined as history of invasive malignancy, except if the patient has received a treatment and has displayed no clinical signs and symptoms for at least 5 years (excludes basal cell carcinoma).
• Infection in the disc or spine, past or present.
• Evidence of active (systemic or local) infection at time of surgery.
• Has a disease process that would preclude accurate evaluation (e.g., neuromuscular disease, significant psychiatric disease).
• Paget*s disease, osteomalacia or any other metabolic bone disease.
• Taking immunosuppressants or steroids which have the potential to interfere with bone/soft tissue healing.
• Morbid obesity (BMI >= 40).
• Is a prisoner.
• A recent history (less than 3 years) of chemical substance dependency or significant psychosocial disturbance that may impact study outcome or participation.
• Participation in a clinical trial of another investigational drug or device within the past 30 days.
• Known allergies to any of the components of the investigational device.
Intraoperative exclusion criteria
• Dural entry during the surgical procedure.
• Newfound intraspinal tumor.
• Involvement of more than two vertebrae levels.
• Epidural fat placement.
• Use of steroid solution.
• Intraoperative decision to use a suction instead of a gravity drainage device.
• Intraoperative decision to leave a hemostatic agent at the surgery site.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2009
Enrollment:	32
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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
ClinicalTrials.gov	NCT00939406
CCMO	NL29487.072.09