ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 06/01/2015

EuroPainClinics® Study II (Prospective Trial) (EPCSII)

This study is currently recruiting participants.
Verified by Europainclinics z.ú., May 2015

Sponsor:	Europainclinics z.ú.
Collaborators:	
Information provided by (Responsible Party):	Europainclinics z.ú.
ClinicalTrials.gov Identifier:	NCT02459392

Purpose

In this prospective multi-centre double-blind trial the effect of the epiduroscopy will be examined in (approximately 300) adult patients with low back pain pain caused by failed back surgery syndrome (FBSS).

Condition	Intervention	Phase
Lumbar Spinal Stenosis	Epiduroscopy Drug: Hyaluronic Acid Drug: DepoMedrol	N/A

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Randomized, N/A
Official Title: EuroPainClinics® Study II (Prospective Randomized Double Blinded Trial)

Further study details as provided by Europainclinics z.ú.:

Primary Outcome Measure:

- Pain as assessed by the Visual analogue scale [Time Frame: 3 years] [Designated as safety issue: Yes]
  All acquired information will be noted in to the special anonymous protocol

Secondary Outcome Measures:

- Pain progress as assessed by global pain scale [Time Frame: 3 years] [Designated as safety issue: Yes]
  All acquired information will be noted in to the special anonymous protocol
- Changes in analgesics drugs consumption as assessed by equianalgesic dose ratios for opioids [Time Frame: 3 years] [Designated as safety issue: Yes]
  All acquired information will be noted in to the special anonymous protocol
- Pain localization as assessed by note of radiating dermatome as neurologic examination [Time Frame: 3 years] [Designated as safety issue: Yes]
  All acquired information will be noted in to the special anonymous protocol

Estimated Enrollment: 300
Study Start Date: May 2015
Estimated Primary Completion Date: November 2016

Estimated Study Completion Date: November 2018

Arms	Assigned Interventions
Epiduroscopy mechanical lysis Epiduroscopy only mechanical lysis	Epiduroscopy Epiduroscopy has two main uses in the pain clinic: Releasing epidural adhesions for the relief of chronic sciatica. Adhesions can form around the lower lumbar nerve roots after decompressive surgery for disc disease or after a bad bout of inflammatory sciatica in the absence of surgery. Epidural adhesions can usually be identified on an enhanced magnetic resonance scan using intravenous gadolinium. They also cause uneven spread of X-ray contrast when performing an epidurogram. Injecting mixtures of local anesthetic and depot steroid around inflamed nerve roots when epidural injections / nerve root blocks have been unsuccessful. The presence of adhesions can prevent epidurally injected drugs from reaching the inflamed nerve roots.
Experimental: Epiduroscopy combination Epiduroscopy together mechanical lysis of epidural adhesions together with epidural drug administration Hyaluronic acid 150 IU and Depo-Medrol 80mg	Epiduroscopy Epiduroscopy has two main uses in the pain clinic: Releasing epidural adhesions for the relief of chronic sciatica. Adhesions can form around the lower lumbar nerve roots after decompressive surgery for disc disease or after a bad bout of inflammatory sciatica in the absence of surgery. Epidural adhesions can usually be identified on an enhanced magnetic resonance scan using intravenous gadolinium. They also cause uneven spread of X-ray contrast when performing an epidurogram. Injecting mixtures of local anesthetic and depot steroid around inflamed nerve roots when epidural injections / nerve root blocks have been unsuccessful. The presence of adhesions can prevent epidurally injected drugs from reaching the inflamed nerve roots. Drug: Hyaluronic Acid Drug: DepoMedrol

Detailed Description:

A small flexible fibreoptic catheter is inserted in sacral hiatus and the areas of concern can be visualized on the screen. Effective drugs like active enzyme: Hyaluronic acid and corticosteroids then can be injected through the same catheter.

With this method we can eliminate adhesions or scar tissue that may be pulling or irritating specific nerve roots.

Indicated for this procedure are patients with low back pain or sciatic patients who have not had a successful result with back surgery or spine surgery and have experienced continued pain after surgery: Failed back surgery syndrome (FBSS). Trial will compare groups of patients after fulfilment inclusion with Failed back surgery syndrome who will undergo interventional pain release procedure epiduroscopy. Elimination of adhesions, or scar tissue will be provided mechanically (grabbers, balloon techniques, by radiofrequency or laser) and with medical support (Hyaluronic acid and Depo-Medrol administration via epidural catheter).

The first group of patients enrolled in to the trial will undergo only mechanical lysis of epidural adhesions (grabbers, balloon techniques, by radiofrequency or laser).

The second group of patients enrolled in to the trial will undergo mechanical lysis of epidural adhesions together with epidural drug administration (Hyaluronic acid 150 IU and Depo-Medrol 80mg).

After first visit in ambulance patients will be about study informed. After agreement patient will be in to the study involved. Specific unique nine digits number will be assigned to each patient. Then patients will be randomized in to groups by special evaluated software created especially for this study. Patients will agree that about range of epiduroscopy (mechanical or combination of mechanical and drug administration) will be informed until the end of the study. This way will be patients blinded.

Second examination will be provided after 6 months. Patients will be in the beginning introduced to doctor only by their unique number. Doctor will be blinded and he will not dispose with information about microinvasive procedure and will examine patient. Data which will be collected: (Visual analogue scale, dermatome where pain is radiating, global pain scale, changes in analgesics drugs consumption). All acquired information will be noted in to the special anonymous protocol. Also patients will anonymously fulfill Oswestry Low Back Disability Questionnaire.

The third examination will be provided after 12 months same way. Patients will be in the beginning introduced to doctor only by their unique number. Doctor will be blinded and he will not dispose with information about microinvasive procedure and will examine patient. Data which will be collected: (Visual analogue scale, pain radiating dermatome, global pain scale, changes in analgesics drugs consumption). All acquired information will be noted in to the special anonymous protocol. Also patients will anonymously fulfill Oswestry Low Back Disability Questionnaire.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Age of 18 years or older
- Written informed consent
- Patients with FBSS
- Magnetic resonance examination evidence of intervertebral disc herniation
- Permanent pain radiating to lower limbs despite previous periradicular therapy or caudal block
- Actual Magnetic resonance imaging: lesion without serious spinal stenosis, lesion without serious radicular compression, lesion without serious intervertebral disc herniation

Exclusion Criteria:

- Patients not capable of consenting
- Pregnant women or women of child-bearing potential
- Cauda equine syndrome

Contacts and Locations

Contacts

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Locations

Czech Republic

Czech republic Recruiting

Praha, Czech Republic
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Contact: Hana Kočanová, MD

Investigators

Study Chair:	Juraj Mláka, MD PhD	R-Clinic

More Information

Responsible Party: Europainclinics z.ú.
Study ID Numbers: 75/EK/15
Health Authority: Slovakia: Ethics Committee