ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
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EuroPainClinics® Study I (Prospective Trial) (EPCSI)

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

Sponsor:	Europainclinics z.ú.
Collaborators:	
Information provided by (Responsible Party):	Europainclinics z.ú.
ClinicalTrials.gov Identifier:	NCT02464553

Purpose

In this prospective multi-centre double-blind trial the effect of the X-ray examinations controlled periradicular therapy should be examined in (approximately 300) adult patients with low back pain pain caused by foraminal stenosis radiculopathy or spinal stenosis.

A periradicular therapy (PRT) is a special radiological, low-risk therapy for chronic back pain caused by wear and tear of the cervical, thoracic, and lumbar spine or a herniated disc or disc bulge. Partially pain might also radiate to the hips or extremities and cause radicular symptoms.

Condition	Intervention	Phase
Lumbar Spinal Stenosis	periradicular therapy (PRT)	N/A

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor), Randomized, N/A
Official Title: EuroPainClinics® Study I (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
- Number of extra PRT procedures [Time Frame: 3 years] [Designated as safety issue: Yes]

Estimated Enrollment: 300
Study Start Date: May 2015
Estimated Primary Completion Date: May 2016
Estimated Study Completion Date: May 2018

Arms	Assigned Interventions
Experimental: Group A 1x periradicular therapy in one intervertebral space, corresponding with pain radiating dermatome	peririadicular therapy (PRT) RTG controlled periradicular therapy (PRT) is a microinvasive interventional pain release procedure. Advantage of targeted pain therapy is exact administration of effective drugs to the nerve root in the area of the thoracic, lumbar or sacral spines.
Experimental: Group B 2x periradicular therapy in two intervertebral spaces, the first corresponding with pain radiating dermatome the second according magnetic resonance visualization where stenosis is situated	peririadicular therapy (PRT) RTG controlled periradicular therapy (PRT) is a microinvasive interventional pain release procedure. Advantage of targeted pain therapy is exact administration of effective drugs to the nerve root in the area of the thoracic, lumbar or sacral spines.

Detailed Description:

Controlled periradicular therapy (PRT) is a microinvasive interventional pain release procedure. Advantage of targeted pain therapy is exact administration of effective drugs to the nerve root in the area of the thoracic, lumbar or sacral spines. It is used like as effective treatment in the patients with radicular pain caused by foraminal stenosis radiculopathy or spinal stenosis.

Spinal stenosis is the narrowing of spaces in the spine which causes pressure on the spinal cord and nerves. Discogenic radicular irritation syndrome is usually caused by protrusion of intervertebral disc or prolapsed disc. The most common is lumbar and sacral radiculopathy which could by exactly verified by CT or magnetic resonance imaging. The biggest profit with the best response on this therapy has patients who are resistant for physiotherapy or per oral medicament therapy.

Intervertebral space verification is provided by X-ray examination imaging. Than in this place is Tuohy needle inserted. Position of Tuohy needle is verified by application of low dose of contrast. When the right position of needle is secured than effective drugs are administered: local anesthetic - Bupivacaine 0,25% (1-2ml) together with corticosteroid injection -Depo-Medrol (40mg). PRT involves several medicable effects: anaesthetic - positive effect on pain transmission in nerve fibers, antichemical - limitation of chemical products from sequestered discs, Anti-edematous - reduction of root nerve oedema, antiphlogistic - inhibition of phospholipase A2, antifibrotic - reduction of scar production.

Trial will compare groups of patients after fulfilment inclusion criteria's who will undergo microinvasive interventional pain release procedure - PRT.

The first group of patients will undergo PRT procedure in the intervertebral space responsible for skin dermatome were the pain is radiating.

Second group of patients will undergo double PRT procedure in the intervertebral space responsible for skin dermatome where the pain is radiating and also in the intervertebral space above where usually is disc lesion responsible for origin of pain localized. 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 type of PRT (one level or two levels) 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, 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. 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, 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 (ODI). If the patient will need to a see a doctor in the reason of deterioration of pain feeling and if the ODI will not increase more than 10% against patient's origin ODI value than one PRT is allowed in the spinal space responding to a pain radiating dermatome during first six months after patients inclusion to trial. Under the same conditions another PRT is allowed during next six months.

When ODI will increase more than 10% against patient's origin ODI value and more than 1 PRT during six month interval will be needed, than patient will be excluded from the study.

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
- Herniated disc, nerve compression, radicular syndromes (vertebrogenic algic syndrome)
- magnetic resonance examination evidence of intervertebral disc herniation
- Pain radiating to the lower limbs
- Disc lesion one level higher than dermatome with pain symptoms

Exclusion Criteria:

- Patients not capable of consenting
- pregnant women or women of child-bearing potential
- Previous spine operations
- Protrusion of more than one intervertebral disc
- Cauda equine syndrome

Contacts and Locations

Contacts

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Locations

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Investigators

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More Information

website

http://www.europainclinics.com/

Responsible Party:	Europainclinics z.ú.
Study ID Numbers:	74/EK/15
Health Authority:	Slovakia: Ethics Committee