ClinicalTrials.gov PRS DRAFT Receipt (Working Version)
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EuroPainClinics® Study III (Prospective Observational Study) (EPCSIII)

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:	NCT02461654

Purpose

In this prospective observational trial the effect of the Disc FX microinvasive therapy should be examined in (approximately 150) adult patients with low back pain.

Condition	Intervention
Disc Herniations	Disc FX

Study Type: Observational
Study Design: Cohort, Prospective
Official Title: EuroPainClinics® Study III (Prospective Observational Study)

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

Biospecimen Retention: None Retained
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 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
- 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

Estimated Enrollment: 150
Study Start Date: May 2015
Estimated Primary Completion Date: May 2017
Estimated Study Completion Date: December 2019

Number of arms: 1
Intervention Details:

Disc FX

Disc FX is an innovative system allowing for a safe and effective approach to a damaged disc without injury to the surrounding structures. The procedure consists of three phases: during the first phase, the disc is punctured with a special needle that functions as a working channel. This needle is used to remove part of the degenerate inner tissue. Then, using a radio-frequency probe, the disc is sealed to minimize the risk of repeated herniation. In the final step, the pathological nerves in the back part of the disc are destroyed with the use of radio-frequency.

Detailed Description:

Patients will be selected from 4 participating clinics from Czech and Slovak republic. Trial will compare evolution of patient's health state, changes of low back pain and other neurological conditions during time period (6 and 12 month) after miniivasive interventional pain release procedure - disc FX.

Back pain due to Lumbar Disc Disease in our population is a very common problem. The treatment options range from physiotherapy to fusion surgery. When all conservative treatment is failed than in some cases with suitable conditions of intervertebral disc is possible to avoid classical disc surgery with minimally invasive surgery techniques. A number of minimally invasive procedures have also been developed in the recent past for its management. One of them is Disc FX procedure. Disc FX is an innovative system allowing for a safe and effective approach to a damaged disc without injury to the surrounding structures. This method provides an option for those people who have not benefited from conservative treatment, and are not yet ready for major surgery. It is a minimal-access procedure performed on an out-patient basis. Its big advantage is the fact that the patient may go home the same day. The procedure consists of three phases: during the first phase, the disc is punctured with a special needle that functions as a working channel. This needle is used to remove part of the degenerate inner tissue. Then, using a radio-frequency probe, the disc is sealed to minimize the risk of repeated herniation. In the final step, the pathological nerves in the back part of the disc are destroyed with the use of radio-frequency.

Trial will compare evolution of patient's health state, changes of low back pain and other neurological conditions during time period (6 and 12 month) after miniivasive interventional pain release procedure - disc FX.

Eligibility

Trial will compare evolution of patient's health state, changes of low back pain and other neurological conditions during time period (6 and 12 month) after miniivasive interventional algesiologic procedure - disc FX.

Sampling Method: Non-Probability Sample
Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Patients who undergo Disc FX therapy

Exclusion Criteria:

- No

Contacts and Locations

Contacts

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Locations

Czech Republic

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Investigators
Study Chair: Juraj Mláka, MD PhD R-Clinic

More Information

Responsible Party: Europainclinics z.ú.
Study ID Numbers: 9N-2015
Health Authority: Slovakia: Ethics Committee