Study Protocol, Statistical Analysis Plan and Informed Consent Form

Efficacy of percutaneous laser disc decompression versus epidural steroid and local anesthetic injection by transforaminal approach in the treatment of lumbar radicular pain

26.09.2022.

Study Protocol

The research is designed as a randomized controlled trial, and will be conducted at the Clinic for Anesthesiology, Reanimatology and Intensive Care Medicine of the Osijek Clinical Hospital Center after obtaining the approval of the Ethics Committee. All patients will receive a written informed consent describing the procedure to be performed, and the procedure will also be explained to them orally. After signing the informed consent, patients will be divided into 2 groups depending on whether there is diascorradicular contact or not, and then within each group depending on the method (ESI or PLDD).
Subjects will be between the ages of 18 and 65 who agree to participate in the study, which they confirm by signing the informed consent, have unilateral lumbar radicular pain that does not respond to conservative treatment, disc herniation at one level, MR verified disc herniation, pain intensity measured with the VAS scale >5. The obtained data will be statistically processed.
Exclusion criteria will be: patients younger than 18 and older than 65 years, refusal of the patient to participate in the research, central stenosis of the lumbar canal, lumbar radicular pain caused by causes other than intervertebral disc herniation, pregnancy, allergy to steroids, local anesthetics, fentanyl, midazolam and contrast agent, positive history of prolonged bleeding, local or systemic infection, previous lumbar spine surgery, opioid abuse, proven inflammatory rheumatic disease and inflammatory bowel disease in the active phase, and other acute infections.
To observe a mean effect in the difference of numerical variables between four independent groups of subjects, with a significance level of 0.05 and a power of 0.80, the minimum required sample size is 116 subjects (29 subjects per group) (calculation made using the program G*Power version 3.1.2, Franz Faul, University of Kiel, Germany).
Patients will have 4 measurements. The first measurement will be before the procedure, the second measurement will be at the follow-up examination after one month, the third measurement at the follow-up examination 3 months after the procedure, and the fourth measurement at the follow-up examination 6 months after the procedure. Control MR of the LS spine will be done 6 months after the procedure.
The VAS scale (Visual Analogue Scale) will be used to assess pain intensity. The questionnaires will be SF-36 (Short form health survey-36), Oswestry Disability Questionnaire Index (ODI), Pain Detect, Hospital Anxiety and Depression Scale (HADS), and the Pittsburgh Sleep Quality Index (PSQI). .
From the clinical examinations, the Lasegue test, the toe-heel test and the flexion test will be performed. Among the laboratory tests, the level of interleukin 6 (IL-6), C-reactive protein (CRP), leukocyte count and differential blood count (DKS) will be determined. The mentioned parameters will be analyzed in three visits: before the procedure, one month after the procedure and after 6 months.

Statistical Analysis Plan

Categorical data will be represented by absolute and relative frequencies. Numerical data will be described by the arithmetic mean and standard deviation in the case of distributions that follow the normal, and in other cases by the median and the limits of the interquartile range. Differences in categorical variables will be tested with the 2 test, and if necessary, with Fisher's exact test. The normality of the distribution of numerical variables will be tested with the Shapiro-Wilk test. Differences of normally distributed numerical variables between two independent groups will be tested with Student's t test, and in case of deviation from normal distribution with Mann-Whitney U test. Differences of normally distributed numerical variables in case of 3 or more independent groups will be tested by analysis of variance (ANOVA), or Kruskal-Wallis test (Post hoc Conover). Differences of normally distributed numerical variables between 4 measurements will be tested by analysis of variance for repeated measurements, and in case of deviation from normal distribution by Friedman test. The association of normally distributed numerical variables will be assessed by Pearson's correlation coefficient r, and in case of deviation from normal distribution by Spearman's correlation coefficient ρ (rho). All P values will be two-sided. The significance level will be set at =0.05. For statistical analysis, the statistical program MedCalc Statistical Software version 19.1.7 (MedCalc Software Ltd, Ostend, Belgium; https://www.medcalc.org; 2020) and SPSS (version 16.0, SPSS Inc., Chicago, IL, NOW).

Informed Consent Form (ICF)

Efficacy of percutaneous laser disc decompression versus epidural steroid and local anesthetic injection by transforaminal approach in the treatment of lumbar radicular pain

Dino Budrovac, MD

We invite you to participate in research for the purpose of writing a doctoral dissertation under the title:
"Effectiveness of percutaneous laser disc decompression versus epidural steroid injection through a transforaminal approach in the treatment of lumbar radicular pain – a prospective randomized controlled study research is conducted by Dino Budrovac, MD. under the mentorship of Assoc.Prof.Ivan Radoš,MD,PhD, Head of the Clinic for Anesthesiology, Reanimatology and Intensive Care, Head of the Institute for pain treatment, Clinical Hospital Center Osijek , University of J.J. Strossmayer in Osijek, Faculty of Medicine Osijek, Department of Anesthesiology, Reanimation and Intensive Care.
As researchers, we have an obligation to inform you about the purpose of the research. Please read this one notice in full. Before agreeing to participate in the research, you can ask us questions. Consent to participate in the research is voluntary.
Lumbar radicular pain is defined as pain in the lumbar region of the spine, with propagation to the legs (sciatica). It is a major public health, social and economic problem in modern society, and one of the most common reasons that patients visits family doctors. It is estimated that 80% of the world's population experiences pain in the lumbar spine at least once during their lifetime. In order to avoid systemic and unwanted effects of analgesics, general or regional anesthesia and long-term and extensive operations are used minimally invasive procedures in the treatment of the mentioned conditions. Epidural steroids injections, as well as percutaneous laser disc decompression are some of these procedures.
We want to investigate which method is more effective depending on discoradicular contact. In proving the above, we need your help and cooperation.
The research will be conducted at the Clinic for Anesthesiology, Reanimatology and Intensive Care, Institute for Pain Management, Clinical Hospital Center Osijek. We will use structured questionnaires, the completion of which will last 30 minutes, and with which we will examine the intensity of the pain, the presence of a neuropathic component, the degree disability, general health, anxiety and depression, pain experience and sleep quality. Blood sampling and clinical tests will be performed initially and at follow-up examinations. After 6 months, a control magnetic resonance of the lumbosacral spine will be done. After data is collected, statistical data processing will be carried out. The anonymity of the respondents is guaranteed.
If you have additional questions regarding this research, feel free to contact us on the mobile number: 099/516 24 89