INFORMED CONSENT

Dear (candidate volunteer/legal representative of the prospective volunteer),

We invite you to participate in the research titled "Investigation of the Clinical Efficacy of Local Anesthetic Agents in Interlaminar Epidural Steroid Injections for Chronic Neck Pain" conducted at Ondokuz Mayıs University Faculty of Medicine Hospital.

Before deciding whether to participate in this research, you should understand the purpose and method of the research, the potential benefits, risks, and discomforts of this research for the volunteer participants, and make your decision freely within the framework of this information. Therefore, it is crucial that you read and understand this form. This form contains the written information provided to you verbally by us, the research directors. Before signing the form, please take the time to carefully read the following information, which was also provided to you verbally. If you agree to participate, you will receive a copy of this form, signed by you and the witness present during the information session, for safekeeping.
Participation in the research is entirely voluntary. You also have the right not to participate in the study or to withdraw from it at any time after participation. In either case, you will not be subject to any penalties or loss of rights. Please take the time to carefully read the information below and, if you wish, discuss this with your private or family doctor. Your questions will be answered by the physician responsible for the study.

Research Supervisor

(Prof. Dr. Fatih ÖZKAN)
(O.M.Ü. Algology Department Faculty Member)

(Date-Signature):

STUDY TITLE (FULL TITLE OF THE STUDY)

Clinical Efficacy of Local Anesthetic Agents with Interlaminar Epidural Steroid Injection for Chronic Neck Pain: A Prospective, Observational Study

WHAT IS THE SUBJECT AND PURPOSE OF THE STUDY?

The primary objective of our study is to investigate whether the addition of local anesthetic agents to epidural steroid injections in patients with chronic cervical pain has a positive effect on the success of the procedure and its clinical effectiveness. Secondary objectives of our study are to evaluate other factors that influence the success of cervical epidural steroid injections.

YOUR RIGHTS TO PARTICIPATE IN/OUT OF THE RESEARCH AND THE RESEARCHER'S ASSURANCE TO PROTECT YOUR RIGHTS:

Participation in this study is entirely voluntary. You may decline participation in the study or withdraw at any time after it begins. There will be no penalty or loss of any rights incurred in the event of non-participation, withdrawal from the study, or withdrawal from the study. You or your

Volunteer signature:

legal representative will be notified if new information concerning the research topic becomes available that may affect your desire to continue the research.

The results of the study will be used for scientific and educational purposes. All information obtained from you will be used solely for research purposes and will be kept confidential. Your identity, if any, will be protected when the study is published.

(No audio, photographs, or video recordings will be used.)

PROCEDURES TO BE APPLIED IN THE STUDY:

An epidural injection contains a steroid or a steroid plus a local anesthetic agent. Through the epidural space, the medication reaches the compressed or affected spinal nerve, reducing inflammation and edema in that area, eliminating pressure and interference on the nerve, and relieving pain. Interlaminar technique: The medication is administered into the epidural space through the middle of the spine. The medication diffuses freely around the nerves. The goal of an epidural steroid injection is to deliver the medication as close to the area causing the pain as possible. The procedure is performed in a completely sterile and aseptic operating room under continuous C-arm imaging. General anesthesia, i.e., anesthesia, is not required during the procedure. The procedure takes approximately 10 minutes. The procedure is an outpatient procedure, meaning most patients do not require hospitalization before or after the procedure. The patient arrives 15 minutes before the procedure and is prepared for the procedure. The patient is removed from their regular clothing and put on a gown. They are placed face down on a special table where the procedure will be performed. A thin pillow is placed under the abdomen to align the lumbar curve. The algiologist continuously monitors blood pressure and blood oxygen levels using monitors. The area around the waist and neck where the procedure will be performed is wiped several times with an antiseptic solution to remove any microbes and cleanse the skin. The procedure site is covered with sterile surgical drapes, and the area to be treated is anesthetized with a fine needle. Under continuous imaging with a computer-assisted C-arm microscope, a special needle is inserted through the skin into the planned injection site. The needle is advanced into the epidural space under continuous imaging. A very small amount of radiopaque material, visible under X-ray, is injected to confirm the needle location and the distribution of the medication. Once the optimal needle position is confirmed, the injection begins. The patient may feel a slight fullness and pressure in the lower back. After the injection is complete, the needle is removed and the procedure is terminated.

During the evaluation, patients will be divided into two groups. The first group will include those who received a cervical epidural injection of betamethasone 6 milligrams (1 milliliter) + 4 milliliters of saline, totaling 5 milliliters. The second group will include those who received a cervical epidural injection of betamethasone 6 milligrams (1 milliliter) + 0.5% bupivacaine 5 milligrams (1 milliliter) + 3 milliliters of saline, totaling 5 milliliters. Patients who have received a cervical epidural steroid injection will be interviewed immediately after the procedure. Magnetic Resonance images (MRI) will be digitally evaluated to determine the level of radiculopathy. Pain intensity before and 1 week, 1 month, 3 months, and 6 months after the cervical interlaminar epidural steroid injection will be assessed using the Numerical Rating Scale (NRS) and Neck Disability Index (NDI) and recorded in their files. Additionally, the patient's contact information, age, gender, marital status, occupation, any previous cervical surgeries, pain location, pain duration, pain intensity, and current painkillers will be recorded. The nurse observation form will inform the patient whether local anesthetic was administered during the procedure. Any complications that occurred during the procedure will be reported on the nurse observation form.

WHAT I MUST DO?

Volunteer signature:

Each step implemented within the scope of the study will be implemented in accordance with the procedures used in routine algology practice. These are procedures. Your responsibility is to trust your physician and follow their instructions completely. If you have any questions or concerns, please feel free to discuss these matters with your physician. You will be informed if there is no clinical benefit to you regarding the reasonably expected benefits of the study.

WHAT IS THE NUMBER OF PARTICIPANTS?

The number of volunteers participating in the study is 60.

HOW LONG WILL PARTICIPATION LAST?

The expected duration for participation in this study is 6 months after the epidural injection.

WHAT IS THE COST OF PARTICIPATION IN THE STUDY?

The study is based on observation of routine practices. There is no cost to you. Participants will not make any additional payment for the study.

WHAT ARE THE POSSIBLE SIDE EFFECTS, RISKS, AND DISCOMFORTS OF PARTICIPATION IN THE STUDY?

Our study is aimed at patient comfort. Patients with diabetes may experience a deterioration in blood sugar levels for 1-2 weeks, and additional medication may rarely be necessary. According to literature, infection is a common occurrence in patients receiving epidural steroid injections, occurring in 1 in 40,000-60,000 patients. However, by performing the procedure in an operating room under absolutely sterile conditions and taking additional precautions, this risk is minimized. Temporary headaches may occur, and nerve damage is also very rare. Fluid retention may occur due to the steroid used. This can be prevented by adhering to a salt-free diet for the first week. While all of this information is available in medical textbooks and literature, all necessary precautions are being taken to ensure the safety of the procedure, and all the risks listed are minimized. Please inform your physician if you experience any discomfort.

PREGNATION AND BIRTH CONTROL

Pregnant and breastfeeding women, children, and elderly patients were excluded from the study.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATION IN THE STUDY?

The aim of this study is to evaluate whether adding local anesthetic to cervical epidural steroid injections increases the success of the procedure in the treatment of patients with long-standing neck pain.

CONTACT PERSON(S)

Name: Fatih

Surname: ÖZKAN

Phone: 05385928006

If you have questions not mentioned above, they will be answered in this section.

Additional questions and answers from the volunteer

There are no additional questions.

Volunteer signature:

CONSENT / APPROVAL / CONSENT

I have read the information section regarding the research whose subject and purpose are specified above and have been informed, first verbally and then in writing, by the undersigned. I fully understand the scope and purpose of the study in which I have been asked to participate, and my responsibilities as a volunteer.

I had the opportunity to ask and discuss the study and received satisfactory answers. The potential risks and benefits of the study were also explained to me verbally. I understand that I am participating in the research voluntarily, that I can withdraw from the research at any time, with or without justification, and that I may be excluded from the research by the researcher regardless of my wishes.

Under these conditions:

1) I agree to participate in this research voluntarily, without any pressure or coercion.

2) If necessary, I consent to the access of my personal information to the persons, institutions, and organizations specified in the legislation.

3) I consent to the use of the information obtained in the study (on the condition that my identity remains confidential) for publication, archiving, and, if necessary, for scientific contribution.

I consent to participate in this research without further explanation, without being under any pressure, and with full knowledge.

Volunteer's (in their own handwriting)

Name-Surname:

Date:

Signature:

(If necessary) For those under guardianship or custodianship, their parent or guardian (in their own handwriting)

Name-Surname:

Date:

Signature:

Translator's (in their own handwriting)

Name-Surname:

Date:

Signature:

If applicable, the person who witnessed the consent process from beginning to end (in their own handwriting)

Name-Surname:

Date:

Volunteer signature:

Signature:

If the volunteer has a language/communication problem:

I have fully translated all the explanations you provided to the volunteer. I have read and translated all pages of this four-page form, which includes the information and consent sections. The information I have translated has been understood and approved by the volunteer.

I have provided the above-mentioned volunteer/legal representative with information regarding the purpose, content, methodology, benefits and risks of the research, and the volunteer's rights. The volunteer/legal representative has also reviewed this form in detail and signed it.

Person Making the Explanations:

Name-Surname:
Signature:
Date (day/month/year):…/…./…..

This Informed Consent Form, consisting of a total of 5 (five) pages, was prepared in two copies, one of which was delivered to the volunteer.

Volunteer signature: