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COMPARING AUTOLOGOUS BLOOD, CORTICOSTEROID, AND THEIR COMBINED INJECTION FOR TREATING LATERAL EPICONDYLITIS

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INFORMED CONSENT FORM

PLEASE TAKE THE TIME TO READ THIS DOCUMENT CAREFULLY

We invite you to the research conducted by Op. Dr. Albert Çakar, " Comparing Autologous Blood, Corticosteroid, and Their Combined Injection for Treating Lateral Epicondylitis". Before you decide whether or not to participate in this research, you need to know why and how the research will be conducted. Therefore, it is of great importance to read and understand this form. If there are things you do not understand or are not clear to you, or if you would like more information, ask us.

Participating in this study is entirely voluntary. You have the right not to participate in the study or to withdraw from the study at any time after participating. Your response to the study will be interpreted as your consent to participate in the study. Do not be under anyone's pressure or suggestion when answering the questions on the forms given to you. The information obtained from these forms will be used entirely for research purposes.

1. Information about the research:

a) Purpose of the Study: Measurement of muscle strength with hand dynamometer and evaluation with PRTEE (Rated Tennis Elbow Evaluation) score and treatment results of patients who received methylprednisolone + prilocain HCL, autologous venous blood + prilocain and methylprednisolone + autologous venous blood + prilocain HCL in the treatment of lateral epicondylitis.
b) Reason for Research: Scientific research
c) Estimated Duration of the Research: 8 months
d) Number of Participants/Volunteers Expected to Participate in the Research: 200
e) Place(s) where the research will be conducted: Istanbul Training and Research Hospital Polyclinics

2. Information about the Process

Muscles, joints and soft tissues around joints can be affected due to trauma, rheumatic and metabolic diseases, some psychological diseases, and cerebrospinal injuries. In these cases, pain, numbness, loss of sensation and movement in the affected area, fluid accumulation in the joint, muscle spasm/spasticity, complete or partial loss of strength (paralysis) in the whole body or in a region, resulting in loss of function and decrease in quality of life may occur. Injection therapy is the application of one or more substances such as dry needle, local anesthetic, cortisone, hyaluronic acid, PRP, botulinum toxin, autologous blood to the appropriate area with an injector. If necessary, auxiliary methods such as EMG and ultrasound can be used during these applications. These applications are very helpful in both diagnosis and treatment. Most of the time, it relieves complaints such as pain and limitation of movement in a shorter time, reduces unnecessary medication use, and stops the intra-articular inflammatory process. The risk of side effects and harm is very low, and it allows taking fluid for analysis, removing unwanted fluid, and administering the therapeutic/supportive substance in the same session.

Possible Risks and Complications

1. A temporary increase in pain may occur during or after the application.
2. There may be skin redness and swelling at the injection site.
3. In intra-articular applications, there may be a possibility of periarticular injection.
4. Crystal synovitis may develop during steroid-cortisone applications.

Researcher
Name-Surname: Op. Dr. Albert Cakar
Signature:

Assistant researcher
Name-Surname: Dr. Özgür Doğuş Gözlü
Signature

5. Other possible side effects may include nausea, dizziness, low blood pressure, palpitations.
6. Very rare important side effects; heart rhythm disturbance, fainting, nerve-muscle-tendon injury/rupture, allergic reactions, infection.
7. Despite all care and attention, pneumothorax (air escape to the chest) may occur, especially in dry needling applied to the back.
8. The possibility of bleeding is higher in patients using blood thinners. The doctor should be informed about this before the procedure.

Risks are rarely seen in the presence of experienced medical personnel and sufficient and appropriate medical equipment.

Things to Consider After Treatment

Excessive movements should be avoided, you should rest, the injection area should not be touched and no other substance should be applied.

3. Consent to Participate in the Study:

I have read the information above that must be given to the participant/volunteer before the research, and I fully understand the purpose of the study in which I am asked to participate and my responsibilities as a volunteer. Written and verbal explanations about the study were made by the researcher named below, I had the opportunity to ask questions and discuss and received satisfactory answers. The possible risks and benefits of the study were also explained to me verbally. I understand that I can quit this study whenever I want, without having to give any reason, and that I will not face any negative consequences if I quit..

Under these conditions, I agree to participate in this research voluntarily, without any pressure or coercion.

Participant (in his/her own handwriting)

Name-Surname:.....
Signature:

(If any) For Those Under Guardianship;
Parent or Guardian (in own handwriting)
Name-Surname:.....
Sigature:

Note: This form is issued in two copies. One of these copies is given to the volunteer in return for signature, and the other is kept by the researcher.

Researcher
Name-Surname: Op. Dr. Albert Cakar
Signature:

Assistant researcher
Name-Surname: Dr. Özgür Doğuş Gözlü
Signature