Study protoco

Introduction

The study will be a multicenter, randomized, double-blind, follow-up clinical trial.

Neither the examining doctor nor the patient knows which capsule they will receive. Just the test

unlock the codes after completion. The randomization was performed externally, not included in the study

performed by a person.

Number of patients: a total of 105 patients / 21-21 per clinic

(with 7 patients each in three treatment groups)

Three treatment groups

• 35 people physical therapy + Loxacon

• 35 main physical therapy + Placebo

• 35 people only for physical therapy

Physiotherapy takes place according to a uniform protocol.

Physiotherapy 2x30 minutes per week for 5 weeks (10 times in total).

The course of the investigation

1st visit: selection, filling in questionnaires

2nd visit: after the 10th exercise session, while taking Loxacon/placebo, filling in questionnaires

3rd visit: Uniformly after another 2 months of taking Loxacon, in all three groups,

completing questionnaires

After the first 5 weeks, all three branches will receive enough Loxacon capsules for 2 months!

The parameters to be tested

▪ WOMAC test

▪ VAS test

▪ EQ-5D-5L quality of life test

▪ Goniometer angle measurement(ROM)

The test is completed by patients who participated in more than 70% of the treatment!

Monitoring of side effects

It is the duty of the doctor of the given center - who reports to the investigator.

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Pain reliever use

If it is necessary to take painkillers, paracetamol can be used uniformly, which

is recorded.

The primary research objective:

How does Loxacon - as a dietary supplement - capsule work in osteoarthritis of the knee joint

on the pain and function of patients with

The secondary research objective:

How Loxacon capsules work for patients with knee osteoarthritis

quality of life?

SELECTION CRITERIA

1. According to the ACR (American College of Rheumatology) knee arthrosis criteria,

knee arthrosis supported by an imaging procedure (comparative knee X-ray). Both

in the case of knee involvement, the more complaining knee will be examined!

2. A patient reporting knee pain characteristic of knee arthrosis for at least 3 months, where the VAS

value 40-70 mm.

3. With a diagnosis of mild and moderate knee arthrosis.

4. Male or female patients between the ages of 40 and 80.

5. With a BMI between 25-35.

EXCLUSION CRITERIA

• Intra-articular corticosteroid within 3 months before starting treatment

injection.

• Intra-articular hyaluronic acid treatment within 6 months or such treatment during the examination

treatment.

• Physiotherapy treatment received within 3 months prior to the start of the treatment.

• NSAID changed within 3 months prior to treatment or during treatment, or chondroprotective treatment.

• In inflammatory rheumatological diseases (RA, SPA, APs, crystal arthropathies, etc.) suffering patient.

• Knee surgery within 6 months prior to the examination.

• Presence of a metal implant in the knee joint.

• Any patient with a knee fracture.

• Patients who had a knee joint injury within 6 months prior to the examination.

• Patients with a palpable fluid collection in the knee or Baker's cyst.

• Uncooperative patients, patients with inadequate mental or psychological status.