

# **COVER PAGE**

## **Informed Consent Form**

**OFFICIAL TITLE: Comparison between the ligation and hemorrhoidopexy technique and the conventional ligation of hemorrhoidal arteries using ultrasound: a prospective, randomized controlled study**

**BRIEF TITLE: Ligation and Hemorrhoidopexy Technique Versus Ligation of Hemorrhoidal Arteries Using Ultrasound for Hemorrhoids**

**UNIQUE PROTOCOL ID: Hemorrhoids RCT**

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## Informed Consent Form

### **Research Protocol: Comparison between the ligation and hemorrhoidopexy technique and the conventional ligation of hemorrhoidal arteries using ultrasound: a prospective, randomized controlled study**

#### **1. Purpose of the trial**

The purpose of this study is to compare two techniques for treating hemorrhoids, the ligation and hemorrhoidopexy technique and the conventional ligation of hemorrhoidal arteries using ultrasound, in patients with non-complicated hemorrhoids.

#### **2. Procedure**

Participants will be admitted in the Department of Surgery of the University Hospital of Larissa in order to be operated for hemorrhoids. Randomly, each patient will be allocated to one treatment group. In the first group ligation of the hemorrhoidal arteries using ultrasound will be performed, while in the second group, the patients will be submitted to ligation of the hemorrhoidal arteries and hemorrhoidopexy. Postoperatively, the patient will be hospitalized in the clinic. The patient will be discharged from the hospital when it will be medically safe to be released. During hospitalization regular measurements, including the level of pain, mobilization, or presence of adverse effects, will be performed. The patient will be summoned to answer to specific questions at predefined time intervals, regarding the remission of the symptoms, the current level of pain, the occurrence of adverse effects or complications, the satisfaction level regarding the operation and the overall quality of life. Maximum follow up will be 1 year.

#### **3. Hazards and Adverse effects**

Possible adverse effects include hypotension, nausea, vomiting, headache, urinary retention and bleeding at the operative site. Other complications that may occur include recurrence of the disease, oedema, hematoma, infection and stenosis at the operative site. Nevertheless, providence for the treatment of complications has been included.

#### **4. Expected Benefits**

This research compares two operative techniques for the treatment of hemorrhoids. The resulting data will help to determine the operative technique with the higher symptoms remission rate, the shorter operative time, the fewer postoperative complications and the shorter hospitalization time.

#### **5. Publication of Data**

The participation in this research project implies that you consent to the future publication of the trial results, provided that this information will be anonymous and the individual data of each participant will not be disclosed. The data that will be collected, will be encoded with a serial number and as a result, your name will not appear anywhere.

#### **6. Information**

Do not hesitate to ask questions about the purpose or the procedure of the trial. If you have any doubt or question, please ask us for further information.

#### **7. Consent**

Your participation in this trial is voluntary. You are free not to consent, or terminate your participation whenever you wish.

#### **8. Informed Consent**

I read this form and I understand the procedures that I will follow. I agree to participate in this research trial.

Date: \_\_/\_\_/\_\_

Participant Name and  
Signature

Investigator Signature

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