COVER PAGE
Informed Consent Form

OFFICIAL TITLE: Intraoperative neuromonitoring of pelvic autonomous nerve plexus during total mesorectal excision

BRIEF TITLE: Intraoperative neuromonitoring during TME

UNIQUE PROTOCOL ID: PelIONM
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Informed Consent Form

Research Protocol: **Intraoperative neuromonitoring of pelvic autonomous nerve plexus during total mesorectal excision**

1. **Purpose of the trial**

The purpose of this study is to evaluate the improvement of the anorectal and urogenital urinary function, alongside the postoperative quality of life after the application of pIONM in patients submitted to TME for rectal cancer.

2. **Procedure**

Participants will be admitted in the Department of Surgery of the University Hospital of Larissa to be operated for rectal cancer. Randomly, each patient will be allocated to one intervention group. In the first group pelvic neuromonitoring will be performed intraoperatively, while in the second group, no neurostimulation will be used. Postoperatively, the patient will be hospitalized in the surgery clinic. The patient will be discharged from the hospital when it will be medically safe to be released. Preoperatively and postoperatively, urogenital and anorectal functional assessment will be performed. The patient will be summoned to answer to specific questions at predefined time intervals, regarding the occurrence of adverse effects or complications, the quality of life and recurrence. Maximum follow up will be 1 year.

3. **Hazards and Adverse effects**

Possible adverse effects include surgery-specific complications such as, recurrence of the disease, oedema, hematoma, infection, urogenital dysfunction, sepsis, ICU admission and death. Nevertheless, providence for the treatment of complications has been included.

4. **Expected Benefits**

The resulting data will help to determine the improvement of the anorectal and urogenital urinary function, alongside the postoperative quality of life after the application of pIONM in patients submitted to TME for rectal cancer.

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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