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Informed Consent Form

OFFICIAL TITLE: Neoadjuvant Chemoradiotherapy and Consolidation Chemotherapy for Rectal Cancer: A Randomized Controlled Trial

BRIEF TITLE: Neoadjuvant Chemoradiotherapy and Consolidation Chemotherapy for Rectal Cancer

UNIQUE PROTOCOL ID: NCCCRC
DOCUMENT DATE: August 2022

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Research Protocol:

Neoadjuvant Chemoradiotherapy and Consolidation Chemotherapy for Rectal Cancer: A Randomized Controlled Trial

The purpose of this research protocol is to compare neoadjuvant chemoradiotherapy and consolidation chemotherapy with neoadjuvant chemoradiotherapy and adjuvant chemotherapy for rectal cancer. The study protocol is designed as a prospective randomized controlled study. The comparison of the two groups will be based on early and late postoperative endpoints. In addition, the efficacy of both approaches in terms of the specimen quality characteristics and the oncological outcomes will be evaluated.

1. **Procedure**

The patient will be admitted to the surgical department according to the predetermined procedure. All the necessary preoperative and laboratory examinations will be performed. A multidisciplinary oncology board will follow to determine the optimal treatment. The patient, then, will be randomized to one of the two groups. Following this, the patient will be submitted to the optimal operation for him / her to treat his / her condition. Postoperatively the patient will be monitored in the surgical department according to the existing protocols and guidelines.

2. **Dangers**

The risks are related to the possible postoperative complications from the operation.

3. **Expected benefits**

The research will result to the publication of data - results. Your participation in the protocol implies that you agree with future publication of results, provided that the information will be anonymous, and the names of the participants will not be disclosed. The data that will be collected will be encoded with a number, so that your name will not appear anywhere.

4. **Information**

Do not hesitate to ask questions regarding the purpose or the process of the protocol. If you have any doubts or questions, please ask us to give you clarifications.

5. **Participation**

Your participation in the protocol is voluntary. You are free to disagree or cancel your participation whenever you wish.

6. Informed consent

I have read this form and I understand the processes that I will follow. I agree to participate in the research protocol.

Date: __/__/__

Participant Name and Signature

Investigator Signature

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