COVER PAGE

Informed Consent Form

OFFICIAL TITLE: Comparison of laparoscopic versus open right colectomy for right colon cancer, according to the complete mesocolic excision (CME) principles: a prospective randomized controlled trial

BRIEF TITLE: Laparoscopic versus open right colectomy for right colon cancer

UNIQUE PROTOCOL ID: LORC
DOCUMENT DATE: February 2023
CLINICALTRIALS.GOV ID: NCT05713903

Principal Investigator:
Konstantinos Perivoliotis, MD
Telephone: 00302413501000
Email: kperi19@gmail.com

Sub-Investigators:
Ioannis Baloyiannis, MD, PhD Assistant Professor of Surgery

Study Director
George Tzovaras, Professor of General Surgery
Telephone: 00302413502804
Email: gtzovaras@hotmail.com

Department of Surgery
University Hospital of Larissa
Mezourlo 41110 Larissa
Greece

UNIVERSITY OF THESSALY, DEPARTMENT OF MEDICINE
UNIVERSITY GENERAL HOSPITAL OF LARISSA
Mezourlo, 41110, Larissa
SURGERY CLINIC
Director: Professor Zacharoulis Dimitrios
A 'Building, 2nd Floor, P.G.N. Of Larissa

UNIVERSITY OF THESSALY, FACULTY OF MEDICINE
UNIVERSITY HOSPITAL OF LARISSA
Mezourlo, 41110, Larissa GREECE
GENERAL SURGERY DPT
Chairman: Prof. Zacharoulis Dimitrios
A 'Wing, 2nd Floor, University Hospital of Larissa

Research Protocol:

Comparison of laparoscopic versus open right colectomy for right colon cancer, according to the complete mesocolic excision (CME) principles: a prospective randomized controlled trial

The purpose of this research protocol is to compare laparoscopic versus open right colectomy according to the complete mesocolic excision principles (CME) in patients with right colon 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

Principal Investigator:
Konstantinos Perivoliotis, MD
Telephone: 00302413501000
Email: kperi19@gmail.com

Study Director:
George Tzovaras, Professor of General Surgery
Telephone: 00302413502804
Email: gtzovaras@hotmail.com