

# **COVER PAGE**

**Document Type:**

Informed Consent Form

**Official Study Title:**

General Anesthesia or Combined Spinal- epidural Anesthesia With Ketofol Sedation in Colon Cancer Surgery?

**NCT Number:**

Not yet assigned

**Document Date:**

November 1, 2021

**Principal Investigator:**

Associate Professor. Ayça Tuba DUMANLI ÖZCAN, MD

**Sponsor:**

N/A

**Participating Sites:**

Ankara City Hospital, Çankaya/Ankara/TURKEY

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| <b>INFORMED VOLUNTEER CONSENT<br/>FORM TO PARTICIPANTS IN “GENERAL<br/>ANESTHESIA OR COMBINED SPINAL-<br/>EPIDURAL ANESTHESIA WITH<br/>KETOFOL SEDATION IN COLON<br/>CANCER SURGERY?” STUDY</b> | <b>Document Name:</b> E2-21-1021       |
|   | <b>Release Date:</b> November 1, 2021  |
|   | <b>Page Number:</b> 1/2                |
|   | <b>Approved by:</b> Head of Department |

Informed Consent Form:

The study that we want you to be a participant in: “General Anesthesia or Combined Spinal-epidural Anesthesia With Ketofol Sedation in Colon Cancer Surgery?” This is a research to be conducted to investigate the subject. Patients with colon cancer are planned to participate in the study between January 2022 and January 2023. In our study, the anesthesia method to be applied may vary according to your co-morbidities and anesthesia risk score. Before the operation, vital signs such as blood pressure, ECG, pulse, oxygen saturation will be monitored. After opening your vein and inserting the epidural catheter, general anesthesia or spinal anesthesia will be administered. The local anesthetic used here is bupivacaine, which is frequently used in practice. Patients who do not want this method will be applied in general. During the procedure, slowdown in your heart rhythm, decrease in blood pressure, allergic reactions due to local anesthetics, local and systemic side effects may be observed. Complications that may occur during the procedure will be intervened immediately. In case of side effects, all our equipments and medicines are readily available. If you participate in our study, you will be included in one of the two groups. Our goal in each group is to send you to your service without pain. Pain scoring called Visual Analogue Scale (VAS) will be used to monitor your pain intensity.

Your condition will be followed up by the researcher before, during and after the surgery. Postoperative pain scores, your NG tube withdrawal time will be followed in terms of the time you start eating.

Your participation in the research is voluntary and you can withdraw from the research at any time, without incurring any penalty, without losing any of your rights. The treatments that will be applied to you will not change with the study, your planned treatment will be applied exactly.

Investigators, polling persons, Ethics Committee, Institution and other relevant health authorities may have direct access to your original medical records, but this information will be kept confidential. By signing the written informed consent form, you or your legal representative consent to such access.

In accordance with the relevant legislation, the records that will reveal your identity will be kept confidential. will not be disclosed to the public; Even if the research results are published, your identity will remain confidential.

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|  |   | <b>Page Number:</b> 2/2                |
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You or your legal representative will be notified in a timely manner as new information becomes available on the subject of the research that may affect your willingness to continue participating in the research.

Below are the people you can contact and the phone numbers you can reach 24 hours a day, so that you can get more information about the research or your rights.

Associate Professor. Ayça Tuba DUMANLI ÖZCAN, MD -+90 505 715 41 25

The period for this research starts with the pre-operative period and ends at the 24th hour after the operation.

“I have read all the statements in the Informed Consent Form. Written and verbal explanations regarding the research, the subject and purpose of which are stated above, were given to me by the physician whose name is mentioned below. I know that I participated in the research voluntarily and I can leave the research at any time with or without justification. I agree to participate in the research in question voluntarily, without any pressure or coercion.

Volunteer’s Name and Surname :

Signature :

Date :

Investigator’s Name and Surname :

Signature:

Date: