European Society of Anaesthesiology and Intensive Care

Patient information to the study:

ENCORE: Effects of aNesthesia in COloREctal cancer outcome trial: a prospective, international multicentre cohort study

Dear Patient,

We invite you to participate in an observational study by providing some of your medical data. Before deciding whether to take part, we would ask you to read the following information. Please read this leaflet carefully. Your doctor will talk about the study with you and answer your questions.
We will enrol at least 10,000 patients from about 200 hospitals.

Participation in our study is voluntary. If you prefer not to take part or withdraw your consent later, no disadvantages will result for you.

Why is this study carried out?

Outcomes, both short- and long-term, after colorectal cancer surgery may be affected by intraoperative factors, both with regards to how anesthesia is managed and what type of surgical technique is used. Additionally, we know that other preoperative risk factors exist, like age and co-morbid conditions.

This large multicenter international observational study aims to elucidate the three-month and three-year outcomes after colorectal cancer surgery. This is done by evaluating the combination of intraoperative management with the other preoperative risk factors.

How is the study carried out?

Your participation extends over a duration of three years, where we will record your health status at three occasions: before surgery, at three months- and three years after your surgery.

Our research team will collect data on the following:

- your health status (e.g., pre-existing diseases, chronic medication, lab results)
- the type and staging of your colorectal cancer
- the intervention
    - what type of anaesthetic technique was used
    - what type of surgical technique was used

This data can be extracted from your clinical record.
In addition, we ask for your permission to do follow-up at three months and three years after surgery, in some countries this data can be extracted from clinical records, but in other

countries we need to ask you, the patient, for this data. Therefore, we would like to ask your permission to call you.

What are the possible benefits of taking part?

Participation in the study will not necessarily benefit you during your hospital stay. The information we get from this study will improve our understanding of anaesthesiologic care during colorectal cancer surgery, and this might lead to improvements in care in the future.

What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks.

Do any additional costs arise?

By taking part in the study, neither you nor your medical insurance will face any additional costs.

What is expected from me?

Information about your outcome after surgery is the focus of the study. Therefore, it is of importance that we can reach you by telephone. If your contact data changes before we have gotten in touch with you, please inform us.

Is it possible to withdraw from the study during its course?

You are under no obligation to take part and declining to be involved will not affect the care you receive. If you agree to participate but then change your mind, you are still free to withdraw at any point, and this will not affect the care you receive. If you decide to withdraw from the study no further data will be collected, but data that has already been collected, and encoded (identified by a number) will remain pseudonymised and used in subsequent analyses to be scientifically valid. Indeed, removal of already collected data would undermine the scientific, and therefore the ethical, integrity of the research. Please talk to your local investigator if you decide to opt out.

Information about data protection

According to the General Data Protection Regulation (GDPR), you have the right to be informed about how your data are protected and what are your rights regarding the processing of your personal data. For this study, the data controller (person, company, or other body determines the purpose and means of personal data processing) is the European Society of Anaesthesiology and Intensive Care (ESAIC), Rue des Comédiens 24, 1000 Brussels,

Belgium. Therefore, ESAIC is responsible for looking after your data and using it properly by respecting your rights. ESAIC's Data Protection Officer can be contacted at privacy@esaic.org

ESAIC has a legitimate interest to process your personal data to conduct the clinical study. The benefit of this study will be to develop scientifically founded recommendations for anaesthesiologists and surgeons caring for patients during colorectal cancer surgery. Such processing is also necessary for scientific research purposes. And to ensure your safety and the integrity of the results of the study, ESAIC also has a legal obligation to process your personal data. Such processing is necessary in the public interest in the field of public health.

The data collected reflect your current clinical situation, some of your background, the results of examinations carried out within the context of care of your health in accordance with the current standards and the results of examinations required by the protocol. All the personal data that could identify you directly (e.g. your name or date of birth) will be replaced by an identification code (pseudonymisation) and will be stored at locked cabinet/office in your institution/hospital, accessible to authorised personnel only. The study doctor and the medical team have a duty of confidentiality with respect to the data collected. This means that all your personal data, which is collected about you that leaves the clinic, does not allow you to identify yourself directly. The study doctor and the medical team will, therefore, be the only persons who can establish a link between the data transmitted throughout the study and your medical records.

The data kept in your hospital will be deleted after archiving period, duration of archiving period is determined by local law. All the coded data relating to the study will be stored electronically at least 10 years. At the end of this period, the data will be destroyed or anonymized. The anonymization process means that data can no longer be used to identify a person by using all the means likely reasonably to be used, the process being irreversible. We only transfer the coded data to third parties if this is permitted by law.

The above-mentioned coded data will be collected by the study site and shared to European Society of Anaesthesiology and Intensive Care in Belgium, Ethic Committees, Regulatory Authorities, and to third parties acting on their behalf.

Your data might be transferred to a country that may not have the same level of personal data protection as your country. If your data is transferred outside of EU, ESAIC is responsible for protecting your personal data. It will ensure that either the country that will receive your data is recognized as having an adequate level of data protection, or appropriate safeguards will be put in place by ESAIC to ensure the protection of your personal data. You have the right to ask for a copy of these safeguards by contacting the Data Protection Officer of ESAIC (privacy@esaic.org).

According to the GDPR, you have the right to access and correct the personal information about you, and to restriction or object to its use or storage. Please, note that these rights are not absolute and will be subject to a case-by-case analysis by the Data Protection Officer of ESAIC. If you have any questions or if you want to exercise your personal data protection rights as a participant in this study, please liaise with the study doctor or research team. They will then be able to direct your questions to the ESAIC DPO. You should be aware that contacting any external body carries the risk of you losing your anonymity.

If you believe that the processing of your data infringes GDPR, you have the right to lodge a complaint with your Country specific Data Privacy Authority.

Department of Personal Data Protection
Level 6, Kompleks Kementerian Komunikasi dan Multimedia
Lot 4G9, Persiaran Perdana, Presint 4 Pusat Pentadbiran Kerajaan Persekutuan,
62100 Putrajaya, Malaysia.
Phone number: 03-8000 8000
Email address: aduan@pdp.gov.my

Declaration of consent for the research project: ENCORE

This is for local use only – Do not send this back to ESAIC secretariat.

Centre Number:

Study Identifier: ENCORE

Patient Identification Number for this trial: __ __ __ - __ __ __ - __ __ __

Name of Researcher/Site Local Coordinating Investigator: _____

I was informed by _____ about the study. I have received and read the written information and declaration of consent for the above study. I was given detailed written and oral information about the purpose and course of the study, the opportunities, and risks of participating and my rights and obligations. I had the opportunity to ask questions. These were answered satisfactorily and completely.

The following phone number(s) may be used to get in touch with me:

(1) _____

(2) _____

(3) _____

I have been advised that my participation is voluntary and that I have the right to withdraw my consent at any time without giving a reason, without incurring any disadvantages.

I hereby consent to participate in the above study. Yes ☐ No ☐

Place and Date Participant's name and signature

Place and Date Signature of the informing doctor