

THE ENCORE STUDY - Effects of anaesthesia in COloRECTal cancer outcome trial

Fast facts

- Colorectal cancer (CRC) is the third most common cancer in the world with an average mortality (Stages 1-4) of 40% at 5-years.
- The 30-day mortality today is between 1 – 2.5% in the western world, showing a 3-fold reduction in the last 10 year
- Following successful surgery, adjuvant chemotherapy is usually administered in stage II and III colorectal cancers and has been shown to significantly improve overall survival in stage III disease and a trend toward increased disease-free survival in selected patients with stage II disease at high risk of relapse.
- The time to start of adjuvant chemotherapy may play an important role in outcome for patients undergoing CRC surgery with curative intent.
- The risk for cancer recurrence, metastasis and survival after primary surgery for cancer might be affected by several perioperative factors.
- It is important to study short- and long-term outcomes in patients undergoing CRC surgery, comparing epidural vs. no epidural and inhalational vs. total intravenous anaesthesia.

Study Design

International Prospective, observational, multi-centre cohort study (no intervention)

Inclusion Criteria

- Inpatients
- Minimum 18 years old
- Scheduled for elective, index (primary) colorectal cancer surgery for stage I-III
- American Society of Anaesthesiologists (ASA) score between I and III
- Signed written informed consent form when required

Exclusion Criteria

- Uncontrolled renal or liver disease
- Restrictive (limiting mobility) heart failure or ischemic heart disease
- Emergency or semi-emergent surgery for suspected bowel obstruction from colorectal cancer
- Speech, language or cognitive difficulties
- Stage IV colorectal cancer when only palliative surgery is planned or if carcinomatosis is obvious at laparotomy and only palliative surgery is possible.

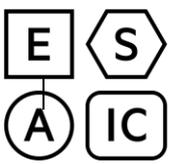
Outcomes

Primary endpoint:

- Time in days from onset of surgery for colorectal cancer to first initiation of planned adjuvant chemotherapy.
- Disease-free-survival (or time-to-recurrence) at 3 years

Secondary endpoint:

- Cancer recurrence at 1 year
- Cancer-related death at 3-years



European Society of
Anaesthesiology and
Intensive Care



Sample Size

We plan to recruit a total of 10000 patients.
Our aim is to have at least 200 large centres recruiting patients from around the world so that this observational study completes recruitment within 1 year. A minimum of 30 patients/centres will be necessary to get good data from each centre.
Each centre will have a local coordinator and each country a national coordinator who will ensure that all participating centres in her/his country perform the study in accordance with the study protocol.

How to get involved

Please fill in the online **call for centre form** and **screening form** on the ESAIC website:
<https://www.esaic.org/research/clinical-trial-network/encore/>

“Does anaesthesia or surgical technique have any benefit for patients in term of earlier start of adjuvant chemotherapy or improve short- or long-term outcomes in patients undergoing index surgery for colorectal cancer (stage I-III)?”

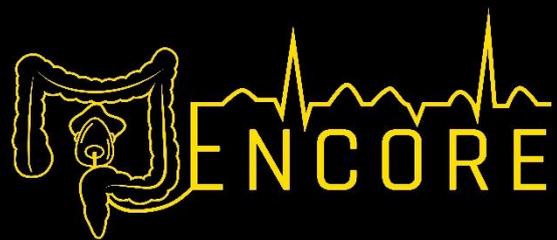
Sponsor

The-ENCORE Study is sponsored by a grant from the European Society of Anaesthesiology and Intensive Care Clinical Trial Network (ESAIC CTN). The aim of the ESA CTN is to provide an infrastructure for clinical research in the fields of anaesthesia, pain, intensive care and emergency medicine by transnational European collaborative studies.

Steering Committee

Chief Investigator: **Max Bell** (Sweden)

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More information

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