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Can optimized postoperative pain management improve outcomes after an operation for oesophageal cancer (cancer of the gullet)?

Submission date
28/01/2026

Recruitment status
Not yet recruiting

Registration date
29/01/2026

Overall study status
Ongoing

Last Edited
30/01/2026

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study is designed to investigate the effects, if any, of different strategies for pain management on the recovery process after an operation for oesophageal cancer (cancer of the gullet).

Who can participate?
Patients aged 18 years and over planned for a minimally invasive (keyhole surgery) operation for oesophageal cancer

What does the study involve?
Participants are randomly allocated to have paravertebral local analgesia or standard postoperative epidural analgesia.

What are the possible benefits and risks of participating?
Both methods used in this trial are approved and we want to uncover differences, if any, in the recovery process. The risks are very small.

Where is the study run from?
This study is led from Uppsala University (Sweden) and also involves academic centers from Norway, Denmark, Finland, Iceland and Italy.

When is the study starting and how long is it expected to run for?
September 2026 to July 2033

Who is funding the study?
1. Nordic Cancer Union
2. Swedish Cancer Society

Who is the main contact?
Dr Jakob Hedberg, jakob.hedberg@surgsci.uu.se

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Study information

Scientific Title
Paravertebral Block AnaLgesia vs. epidural: Assessing Novel Care in Esophagectomy (BALANCE): a multi-center randomized Phase III trial

Acronym
BALANCE

Study objectives
To provide high-level evidence on the benefits/risks of epidural analgesia in minimally invasive esophagectomy.

Ethics approval required

Ethics approval required

Ethics approval(s)
notYetSubmitted

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Health services research, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Oesophageal cancer

Interventions
Randomisation:
Participants are enrolled and randomized consecutively as they are found to be eligible for inclusion in the trial. Randomization is performed no later than 12 h before surgery. If a participant discontinues participation, the participant's trial-specific code will not be reused, and the participant will not be allowed to re-enter the trial.
Randomization will be performed online from within an electronic randomization system, after a multidisciplinary tumor board meeting, once all eligibility criteria have been verified and no exclusion criteria have been fulfilled. Randomization will be stratified by country and level of anastomosis (chest/neck). The electronic randomization module is accessed from each participating site. Treatment allocation will be open-label, among the two intervention arms at a 1:1 ratio of paravertebral block and opioid PCA (intervention) or standard EDA treatment (control).

Intervention:
Participants who are randomized to intervention will receive a paravertebral block at the end of the thoracic phase of surgery. Local anesthetics injected under thoracoscopic vision in 1-4 sites in the intercostal space 3-8 according to local routines. As always, attention to not inject in vessels (aspiration) is crucial. Abdominal port sites are also injected according to local routines. Permitted drugs and combinations are: monotherapy, preferably bupivacaine 2.5 mg/ml (total volume 40-60 ml). Alternatively, ropivacain 3.75 mg/ml (total volume 40-60 ml) can be used.

Dexamethasone or betamethasone IV 8 mg Klonidin 75-150 µg IV (optional per center but same in both arms). In addition, patient-controlled analgesia with opioids according to local protocols is used in this arm.

Control:
Participants who are randomized to control will receive routine EDA according to local routines at level Th6-10. After correct placement of the epidural catheter, a local anesthetic (ropivacaine, levobupivacaine, or bupivacaine) is used and according to in-house protocols, an opioid will be added to the epidural solution.

Follow up:
All primary and secondary outcomes will be recorded 30 days after surgery with the exception of survival which will be followed for 5 years.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Anastomotic leak measured using clinical evaluation, including CT with peroral contrast, at 30 days

Key secondary outcome(s))
1. Postoperative pain measured using Numeric Rating Scale (1-10) and total postoperative opioid use (enteral and parenteral), at baseline and on days 1, 2, 3, 7 and 30 after surgery

2. Risk of overall and procedure-specific complications measured using the Clavien-Dindo Classification at 30 days after surgery

3. Hypotension measured using assessment of blood pressure at up to postoperative day 5

Completion date
28/07/2033

Eligibility

Key inclusion criteria
Adult (≥18 years of age) patients undergoing minimally invasive oesophagectomy with gastric conduit reconstruction due to confirmed cancer (cT1 N+ or cT2-4a any N; M0-1)

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
90 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Epidural analgesia contraindicated, i.e., known uncontrollable hypersensitivity to the components of the chemotherapeutic agents used in the trial regimens
2. Use of anticoagulants precluding EDA use
3. No postoperative nasogastric tube
4. No ability to understand the study in terms of risk and benefits (including language difficulties)
5. The participant has any other severe acute or chronic medical or psychiatric condition or laboratory abnormality that would, in the judgment of the investigator, pose excess risk associated with study participation or that, in the judgment of the investigator, would make the patient inappropriate for entry into the trial

Date of first enrolment
01/09/2026

Date of final enrolment
31/07/2028

Locations

Countries of recruitment
Denmark

Finland

Iceland

Italy

Norway

Sweden

Sponsor information

Organisation
Uppsala University

ROR
https://ror.org/048a87296

Funder(s)

Funder type

Funder Name
Nordic Cancer Union

Alternative Name(s)
The Nordic Cancer Union, NCU

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Norway

Funder Name
Cancerfonden

Alternative Name(s)
Swedish Cancer Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1	26/01/2027	30/01/2026	No	No