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Nordic trial of nasogastric tube use after operations for cancer in the gullet

Submission date 08/12/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/12/2021	**Overall study status** Ongoing	
Last Edited 13/08/2025	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
The mainstay of curative treatment of cancer in the esophagus (gullet) is surgical resection with a part of the stomach used for replacement of the resected esophagus. In Scandinavia, a naso-gastric tube (NG tube) is generally left in place after surgery but the clinical benefits and potential harms of this practice are unclear and because esophageal surgery is laden with feared complications, especially leak on the connection between the stomach remnant and the esophagus (anastomotic leak), many surgeons are reluctant to abandon old routines. We hypothesized that abstaining from NG-tube use is non-inferior to using NG-tube after esophagectomy regarding anastomotic leak and overall complications.

Who can participate?
Adult patients undergoing esophagectomy for cancer in Scandinavia

What does the study involve?
Patients will be randomly allocated to one of two groups, with an equal chance of being in either group (like tossing a coin), to either have a nasogastric tube kept in place after surgery or have this tube removed immediately after surgery.

What are the possible benefits and risks of participating?
The potential benefits of participation are less postoperative discomfort for patients not having an NG tube, but also possibly fewer complications. The potential risks are a slightly higher complication rate.

Where is the study run from?
Uppsala University (Sweden)

When is the study starting and how long is it expected to run for?
From July 2020 to December 2030

Who is funding the study?
Swedish Cancer Foundation (Sweden)

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

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A randomized controlled trial: nasogastric-tube post-esophagectomy complications

Acronym
Kinetic

Study objectives
Omitting the use of nasogastric tube after resection for esophageal cancer with a gastric conduit, is non-inferior to currant practice (postoperative nasogastric tube decompression)

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. Approved 12/10/2021, Etikprövningsmyndighetens (Box 2110, 75002 Uppsala, Sweden; +46 (0) 10-475 0800; registrator@etikprovning.se), ref: 2021-03761
2. Approved 21/07/2021, REK sør-øst B (Gullhaugveien 1-3, 0484 Oslo, Norway; +4722 84 55 11; rek-sorost@medisin.uio.no), ref: 256722
3. Approved 27/06/2022, Center for Sundhed (De Videnskabsetiske Komiteer Blegdamsvej 60, 1. sal, opgang 94A11 2100 København, Denmark; +45 (0)38666395), ref: H-21069333
4. Approved 16/12/2021, The Ethical Committee of Northern Ostrobothnia (the regional medical research ethics committee of the wellbeing services county of North Ostrobothnia, Kajaanintie 50 (NK-sisäänkäynti), OYS Tutkimuspalveluyksikkö N5 (huone N5 133, 1. krs), 90220 Oulu, Finland; +358 (0)50 448 4955; eettinentoimikunta@pohde.fi), ref: EETTMK 85/2021 266§

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Nasogastric tube decompression after resection for esophageal cancer with gastric conduit reconstruction

Interventions
Participants will be allocated to either the intervention or control group. Allocation provided by online randomization with stratification for center, sex, and neck anastomosis (y/n).
Intervention: Immediate posatoperative removal of nasogastric tube
Control: 5-day use of nasogastric tube (current practice).

Intervention Type
Procedure/Surgery

Primary outcome measure
Incidence of an anastomotic leak measured using CT scan with peroral contrast at 7 days and data accrual in an eCRF by 6 weeks post-surgery

Secondary outcome measures

1. Incidence of pneumonia measured using data accrual in an eCRF by 6 weeks post-surgery
2. Overall complications measured using data accrual in an eCRF by 6 weeks post-surgery
3. Length of stay measured using data accrual in an eCRF by 6 weeks post-surgery
4. Health-related quality of life measured using structured interviews at discharge and 6 weeks post-surgery
5. Survival measured using review of survival information in relevant linked registries at 5 years
6. C-reactive protein (CRP) level measured using data accrual of CRP levels in the first 7 postoperative days in an eCRF by 6 weeks post-surgery

Overall study start date
01/07/2020

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. Histopathologically confirmed esophageal or GEJ cancer in locally advanced stages (cT1a N+ or cT1b-4a any N; M0) and considered technically resectable by the local tumor board
2. Age ≥18 years
3. Planned for esophagectomy with gastric conduit reconstruction
4. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
450

Total final enrolment
448

Key exclusion criteria
1. No resection performed (reason specified)
2. Alternative reconstruction method used (Roux-limb/colonic interponate)
3. Surgeon choosing to leave NG-tube (reason specified)
4. No ability to understand the study in terms of risk and benefits (including language difficulties)

Date of first enrolment
21/01/2022

Date of final enrolment
27/03/2024

Locations

Countries of recruitment
Denmark

Finland

Norway

Sweden

Study participating centre
Uppsala University Hospital
Akademiska Sjukhuset
Uppsala
Sweden
75185

Study participating centre
Karolinska Sjukhuset
Karolinska University Hospital
Stockholm
Sweden
17176

Study participating centre
Umeå University
Norrlands Universitetssjukhus
Umeå
Sweden
901 89

Study participating centre
Örebro Universitet
Örebro Universitetssjukhus
Örebro
Sweden
701 85

Study participating centre
Linköpings Universitet
Linköping University Hospital
Linköping
Sweden
581 91

Study participating centre
Lund University
Skane University Hospital
Lund
Sweden
221 85

Study participating centre
The arctic University of Norway
University Hospital of Northern Norway
Tromsø
Norway
9038

Study participating centre
Norwegian University of Science and Technology
St Olavs Hospital
Trondheim
Norway
7006

Study participating centre
Oslo University
Oslo University Hospital
Oslo
Norway
0424

Study participating centre
University of Copenhagen
Copenhagen University Hospital

Copenhagen
Denmark
2100

Study participating centre
University of Southern Denmark
Odense University Hospital
Odense
Denmark
5000

Study participating centre
Oulu University
Oulu University Hospital
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Sponsor information

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Uppsala University

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Sponsor type
University/education

Website
https://www.uu.se/en/

ROR
https://ror.org/048a87296

Funder(s)

Funder type
Charity

Funder Name
Swedish Cancer Foundation (Salary, PI, CAN 2017/1086)

Results and Publications

Publication and dissemination plan
Planned publication of the main findings in high impact peer-reviewed journals.

Intention to publish date
01/07/2026

Individual participant data (IPD) sharing plan
Due to legal restrictions regarding patient data in the participating countries, no raw data can be disseminated in this trial.

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 2.7	06/12/2021	09/12/2021	No	No
Protocol article		16/02/2024	19/02/2024	Yes	No
Abstract results		02/09/2024	30/09/2024	No	No
Protocol file	version 4.0	08/01/2025	13/01/2025	No	No
Results article		31/07/2025	13/08/2025	Yes	No