

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

Submission date 08/12/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/12/2021	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/01/2025	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English Summary

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 nasogastric 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

Contact name
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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 hypothesis
Omitting the use of nasogastric tube after resection for esophageal cancer with a gastric conduit, is non-inferior to current 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-sisääntyänti), OYS Tutkimuspalveluyksikkö N5 (huone N5 133, 1. krs), 90220 Oulu, Finland; +358 (0)50 448 4955; eettintoimikunta@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.

Condition

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 postoperative 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

Overall study end date

31/12/2030

Eligibility

Participant 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

Participant 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)

Recruitment start date

21/01/2022

Recruitment end date

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
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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
Oulu
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Sponsor information

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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