ISRCTN35827514 https://doi.org/10.1186/ISRCTN35827514

Using MRI to predict the success of anticancer treatment before surgery to the esophagus (gullet) and the gastroesophageal junction (gullet-stomach junction)

Submission date
08/05/2018

Recruitment status
Stopped

Registration date
22/05/2018

Overall study status
Stopped

Last Edited
01/03/2021

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Cancer in the esophagus (gullet) and the gastroesophageal junction (gullet-stomach junction) are serious diseases. Despite diagnostic and treatment progress in recent years, only around 1 in 5 (20%) of the patients who gets these diseases can be cured. The best treatment results are achieved with a combination of anticancer treatments (radiation and drug treatment) followed by surgery. This combination therapy is effective on a group level, but for the individual patient it is very hard to know if the radiation therapy and chemotherapy (medicines) will be effective. If this could be known for each patient, a better tailor-made treatment plan could achieved. We want to improve the ability to see who responds well to this treatment before surgery and promising results from MRI in other types of tumors gives us hope that we can do this for esophageal and gastroesophageal junctional cancer as well.

Who can participate?
Adults over the age of 17.

What does the study involve?
Participants are asked to join this study at the time of their diagnosis. The study involves one MRI scan before and one after the anticancer treatment that is given before surgery. The first scan is used instead of the routine method used today (PET-CT) and the second scan is added for the purpose of this study. The scan takes around 60-90 minutes and involves lying on your back in a small space.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. In the future, we hope to be able to use the knowledge gained from this study to formulate new strategies to improve patient survival and quality of life.

Where is the study run from?
This study is run from the Department of Surgical Sciences at Uppsala University Hospital, Uppsala, Sweden.

When is the study starting and how long is it expected to run for?
September 2018 to 2025.

Who is funding the study?
The Swedish Cancer Society (Cancerfonden)
Lions Cancer Fund Uppsala
Swedish Government Grants (ALF)

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

Contact information

Type(s)
Scientific

Contact name
Dr Jakob Hedberg

Contact details
Department of Surgical Sciences
Ing 70
Uppsala University Hospital
Uppsala
Sweden
75185
+46 (0)186116507
jakob.hedberg@surgsci.uu.se

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
PET-MRI for prediction of treatment response to neoadjuvant treatment of cancer in the esophagus and the gastroesophageal junction

Acronym
PREciSE II (Pet magnetic RESonance of Esophagus II)

Study objectives

PET-MRI can combine data from PET with radiomic characteristics of the tumor in order to improve the prediction of complete pathological response to neoadjuvant treatment in esophageal cancer and cancer in the gastroesophageal junction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regional ethics review board Uppsala, 10/07/2018, ref: 2018/226

Study design
We aim to evaluate PET-MRI in a cross-sectional cohort of patients planned for neaodjuvant treatment followed by resectional surgery for esophageal cancer and cancer of the gastroesophageal junction.

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Esophageal cancer and cancer in the gastroesophageal junction.

Interventions
The recruited patient undergoes a PET-MRI at diagnosis and one before surgery. This is a 60- to 90-minute investigation. The surgical specimen is investigated according to clinical routine for TNM (tumour, node metastasis) staging and tumor regression grade according to Becker. The follow up is performed in accordance with clinical routine. After that the patient is followed in our national registries for registration of death and up to 5-year survival rates can be included in future analyses.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The main outcome measure is specificity and sensitivity for prediction of complete pathological response to neoadjuvant treatment. The radiomic results will be calculated by an operated blinded for other clinical data and the score will be entered into a dataset. Other radiologic markers (SUV-max etc) will be entered as well. The pathological examination will also be entered into a blinded dataset and correlation analyses will be performed.

Key secondary outcome(s))
Tumor immune cell population composition in relation to pathological clinical response. Plasma and tumor samples before and after neoadjuvant therapy are frozen and saved for future analysis. In circulating plasma, biomarker assays will be preformed before, during and after neoadjuvant treatment along with appropriate bioinformatic statistical interpretation (Oling, Immunooncology panel). In addition to this, immunohistochemical analyses of tumour material

(CD4, FoxP3, CD8/CD45RO andEn CD20), analyses for immunology gene-expression before and after neoadjuvant treatment (Nanostring, nCounter Immunology ans Inflammation panels) will be performed.

Completion date
31/12/2025

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Esophageal cancer or gastroesophageal junctional cancer Siewert I and II
3. Planned for neoadjuvant treatment and surgery
4. Clinical stage T1-4aN0-3M0

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Cannot undergo MRI due to claustrophobia
2. Implants contraindicating MRI fitted, including pacemaker, pacemaker electrodes, mechanical heart valve, CNS electrodes and cochlear implants
3. Language difficulties making informed consent impossible
4. Renal failure
5. Allergy to contrast medium
6. Pregnancy

Date of first enrolment
01/09/2018

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala University Hospital
Ing 70
75185
Uppsala
Sweden
75185

Sponsor information

Organisation
Uppsala University

ROR
https://ror.org/048a87296

Funder(s)

Funder type
Charity

Funder Name
Lions Foundation (Uppsla, Sweden)

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

The datasets generated during and/or analysed during the current study are not expected to be made available due to Swedish law prohibiting unspecified dissemination of patient-related data or images even if anonymised.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes