

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/05/2018	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/03/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 be 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?

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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 neoadjuvant treatment followed by resectional surgery for esophageal cancer and cancer of the gastroesophageal junction.

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Hospital

Study type(s)

Diagnostic

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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.

Secondary outcome measures

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 and En CD20), analyses for immunology gene-expression before and after neoadjuvant treatment (Nanostring, nCounter Immunology and Inflammation panels) will be performed.

Overall study start date

01/01/2018

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40 patients

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

Sponsor details

Department of Surgical Sciences

Uppsala University Hospital

Uppsala

Sweden

75185

Sponsor type

University/education

Website

<https://www.surgsci.uu.se/?languageld=1>

ROR

<https://ror.org/048a87296>

Funder(s)

Funder type

Charity

Funder Name

Lions Foundation (Uppsala, 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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal with the first results (main outcome) in 2021

Intention to publish date

31/12/2021

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