PDL-1 targeting in resectable oesophageal cancer: a phase II feasibility study of Atezolizumab and chemoradiation (PERFECT)

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON55613

Source
ToetsingOnline

Brief title
PERFECT

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
Esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Roche

Intervention

Keyword: Chemoradiation, Esophageal cancer, PD-L1 inhibtion

Outcome measures

Primary outcome

The primary endpoint is feasibility defined as percentage completion of treatment with atezolizumab. Patients that do not complete treatment with atezolizumab for reasons other than toxicity will be replaced and not included in the analysis of the primary end point.

Secondary outcome

Secondary endpoints are:

• Incidence and severity of toxicity defined according to CTCAE v4.03 and Radiation Oncology Group (RTOG) criteria.

• Percentage completion of chemotherapy and radiation treatment

• Percentage withdrawal rate from surgery

• Incidence and severity of post-operative complications according to the Dindo classification.

• Pathological response according to the Mandard criteria.

• R0 resection rate.

• Progression free survival

• Overall survival

Exploratory endpoints are:

• Potential biomarker development based on assessment of tumour biopsies,

faeces and blood samples and the proposed mechanism of action of study

drugs.

Study description

Background summary

The prognosis of esophageal cancer is poor, despite treatment with chemoradiation and resection. The outcome of the treatment may be improved by the addition of certain forms of immunotherapy, such as atezolizumab, to the treatment. In this study we investigate whether it is feasible.

Study objective

Possibly, outcomes of treatment can be further improved by adding atezolizumab to neoadjuvant chemoradiation. As a first step we aim to know whether the addition of atezolizumab feasible. That is, we want to know how the treatment is tolerated and whether the treatment can be given as scheduled.

Study design

This is a non-randomized feasibility study on the combination of atezolizumab in combination with carboplatin, paclitaxel, and radiation therapy, followed by a resection of the primary tumor.

Intervention

Atezolizumab is added once every three weeks to the standard chemoradation. After 5 administrations surgery takes place.

Study burden and risks

The administration of atezolizumab prolongs the first visit by ~ 90 minutes; then per administration ~ 60 minutes extra are required. (In total 5 administrations)

In rare cases, both taking of blood samples as well the insertion of an infusion needle may be painful.

The extra gastroduodenoscopy can result in bleeding ora perforation may result.

Finally, a patient can have side effects of the study medication. The most

common side effects atezolizumab include fatigue, nausea, decreased appetite, diarrhea, constipation and cough. Because by atezolizumab the immune system is enhanced, specific side effects can occur which have to do with an immune response directed against one's own body. This can manifest itself as an inflammation of the liver, lungs, intestines, pancreas, brains or meninges. It is also possible that the patient is developing diabetes, a too slow or too fast-acting thyroid or adrenal insufficiency. Finally, specific neurological syndromes (Guillain-Barré syndrome, myasthenia gravis) may develop.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Histologically proven adenocarcinoma of the esophagus or gastro esophageal junc

2. The tumor is surgically resectable
3. Patient is fit for surgery

Exclusion criteria

Past or current history of malignancy other than entry diagnosis interfering with prognosis of esophageal cancer

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-07-2017
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Tecentriq
Generic name:	Atezolizumab

Ethics review

Approved WMO

Date:	17-02-2017

Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-02-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-12-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-12-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2016-004744-11-NL
CCMO	NL60011.018.16