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Observational study to evaluate PD-L1 protein expression in Chinese patients with advanced esophageal cancers and head and neck squamous cell carcinoma

Submission date
02/12/2020

Recruitment status
No longer recruiting

Registration date
29/04/2021

Overall study status
Completed

Last Edited
16/11/2023

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Esophageal (food pipe) cancer (EC) and head and neck squamous cell carcinoma (HNSCC) are common cancers with high rates of incidence and mortality (death) in China. However, the levels of PD-L1 protein in Chinese patients with advanced EC and HNSCC are largely unknown. The aim of this study is to determine the prevalence of PD-L1 high expression in Chinese patients with advanced EC and HNSCC.

Who can participate?
Patients aged 18 or older with advanced EC or HNSCC and an available tumor tissue sample

What does the study involve?
PD-L1 protein expression levels are measured from tumor tissue samples.

What are the possible benefits and risks of participating?
Since this study does not provide treatment, there is no direct benefit to the participant. Information learned from the study may help other people in the future.

Where is the study run from?
Merck Sharp and Dohme (China)

When is the study starting and how long is it expected to run for?
November 2020 to December 2022

Who is funding the study?
Merck Sharp and Dohme (China)

Who is the main contact?
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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
8746

Study information

Scientific Title
A multi-center retrospective observational study to evaluate PD-L1 protein expression in Chinese patients with advanced esophageal cancers and head and neck squamous cell carcinoma

Acronym
Exceed

Study objectives
To determine the prevalence of PD-L1 high expression (determined by CPS ≥10 for EC, CPS ≥20 for HNSCC) in Chinese patients with advanced esophageal cancers (EC) and head and neck squamous cell carcinoma (HNSCC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/11/2020, National Cancer Center/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College; National GCP Center for Anticancer Drugs, The independent Ethics Committee (No.17 Panjiayuan Nanli, Chaoyang District, Beijing P.R. China; +86 (0)8610 87788495; cancergcp@163.com), ref: 20/377-2573

Study design
Multi-center retrospective observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Esophageal cancer and head and neck squamous cell carcinoma

Interventions
This is a multi-center retrospective non-interventional study designed to examine PD-L1 protein expression among 920 patients diagnosed with advanced EC and HNSCC at seven participating centers in China. Eligible patients should be 18 years of age or older and able to provide a representative tissue block for PD-L1 analysis.

In all study centers, PD-L1 expression will be determined locally by a pathologist in all samples using the PD-L1 IHC 22C3 pharmDx kit and described in prevalence of CPS ≥10 for EC, CPS ≥20, CPS ≥1 for HNSCC and by key baseline demographic, clinicopathologic parameters, treatment status and other biomarkers.

Sample processing and analysis is estimated to last for 18 months. An interim analysis is planned when 640 samples (two-thirds of the overall sample required) have been analyzed.

Intervention Type
Other

Primary outcome measure
PD-L1 expression determined using the PD-L1 IHC 22C3 pharmDx kit at baseline; this is a qualitative IHC assay using monoclonal mouse Anti-PD-L1, clone 22C3 intended for detection of PD-L1 protein in FFPE tissues using the EnVision FLEX visualization system on Autostainer Link

48. PD-L1 protein expression is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. CPS is defined as follows: CPS = # PD–L1 staining cells (tumor cells, lymphocytes, macrophages) / Total # of viable tumor cells × 100

Secondary outcome measures
Collected at baseline from each center's electronic medical record (EMR) system or by chart review if no EMR exists:
1. Key demographic characteristics (e.g. age at diagnosis, gender, family history of studied disease, history of tobacco use)
2. Clinicopathological parameters (e.g. primary tumor site, tumor stage, histology and grade, metastatic location and number, site and type of tumor tissue sample)
3. Treatment status (e.g. previous lines of therapy, prior curative treatments)
4. Other available biomarkers (e.g. HER2 for EC and HPV status for HNSCC)

Overall study start date
09/11/2020

Completion date
30/12/2022

Eligibility

Key inclusion criteria
General criteria:
1. Patient must have informed consent form (ICF) signed previously, which gives consent for his /her sample to be used in a future study, unless the patient is under conditions accepted by IRB /ERC to waive ICF. Otherwise, the patient must provide a specific written informed consent for this study
2. Patient is 18 years of age or older at diagnosis

Criteria for EC:
1. Patient has histologically or cytologically confirmed diagnosis of adenocarcinoma or squamous cell carcinoma of the esophagus or Siewert type I adenocarcinoma of the EGJ (defined as adenocarcinomas of the lower esophagus with the center located within 1 cm to 5 cm above the anatomic EGJ)
2. Patient has metastatic disease or locally advanced, unresectable disease
3. Patient must have an available FFPE tumor specimen obtained with resection, core needle biopsy or endoscopic biopsy
3.1. Newly-obtained specimen (collected up to 6 weeks prior to the start of PD-L1 IHC test) is preferred to archived one
3.2. Archival tissue block should be no older than 1 year
3.3. Tumor specimen collected from the primary site is preferred to that from the metastatic site

Criteria for HNSCC:
1. Patient has histologically or cytologically confirmed diagnosis of recurrent or metastatic HNSCC that is considered incurable by local therapies. The patient may not have a primary tumor site of nasopharynx (any histology)
2. Patient must have an available FFPE tumor specimen obtained with core or excisional biopsy
2.1. Newly-obtained biopsy specimen (within 90 days prior to start of PD-L1 IHC test) is preferred to an archived one

2.2. Archival tissue block should be no older than 2 years
2.3. Tumor specimen collected from the primary site is preferred to that from the metastatic site
2.4. Decalcified bony specimen is not accepted

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
920

Key exclusion criteria
Patient has only a specimen obtained with fine needle aspirate (FNA) or cytologic specimen

Date of first enrolment
05/01/2021

Date of final enrolment
01/05/2021

Locations

Countries of recruitment
China

Study participating centre
The Cancer Institute and Hospital, Chinese Academy of Medical Sciences (CAMS)
17 Panjiayuan Nanli
Chaoyang District
Beijing
China
100021

Study participating centre
West China School of Medicine and West China Hospital, Sichuan University
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Study participating centre
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Zhong Shan Ophthalmic Center
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Study participating centre
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Study participating centre
The First Affiliated Hospital of Zhengzhou University
No.1 East Jianshe Rd
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Study participating centre
Henan Cancer Hospital
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Sponsor information

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Merck Sharp and Dohme

Alternative Name(s)
MSD United Kingdom, Merck Sharp & Dohme, Merck Sharp & Dohme Corp., MSD

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. Additional documents are not available.

Intention to publish date
30/12/2023

Individual participant data (IPD) sharing plan
The participant-level data will be stored in a Merck internal website with a strict policy.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/11/2023	16/11/2023	Yes	No