

Assessment of Disease Feature and Treatment Pattern of Locally Advanced, Recurrent and/or Metastatic Head and Neck Squamous Cell Carcinoma in China (ADAPT-H&N)

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Study

Planned

Administrative details

EU PAS number

EUPAS103485

Study ID

103486

DARWIN EU® study

No

Study countries

 China

Study status

Planned

Research institutions and networks

Institutions

Shanghai East Hospital Tongji University

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Institution

Contact details

Study institution contact

Shu Peng shu.peng@merck.com

Study contact

shu.peng@merck.com

Primary lead investigator

Ye Guo

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 28/11/2022

Study start date

Planned: 13/02/2023

Date of final study report

Planned: 31/01/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MSD (China) Holding Co., Ltd.

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Drug utilisation

Main study objective:

(1) To describe patient demographics, clinical characteristics in R/M disease (2) To describe the first line systemic treatment distribution in R/M disease (3) To describe patient demographics, clinical characteristics in LA disease (4) To describe the primary treatment approach in LA disease • Overall, and according to tumor location and tumor stage

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective, non-interventional study

Study drug and medical condition

Medical condition to be studied

Squamous cell carcinoma of head and neck

Additional medical condition(s)

Locally Advanced, Recurrent and/or Metastatic Head and Neck Squamous Cell Carcinoma

Population studied

Age groups

- Adults (18 to < 46 years)
 - Adults (46 to < 65 years)
 - Adults (65 to < 75 years)
 - Adults (75 to < 85 years)
 - Adults (85 years and over)
-

Estimated number of subjects

840

Study design details

Outcomes

Demographic variables and disease related variables will be reported using descriptive statistics. Treatment regimens and treatment exposure (if available) will be reported using descriptive statistics for R/M disease Treatment approaches will be analyzed overall and according to tumor locations (lip/oral cavity, oropharynx, hypopharynx, larynx) and tumor stage (III and IVA-B) for LA disease. Description of subsequent systemic treatment in R/M disease Estimation of Time to Next Treatment from initiation of first line systemic treatment in R/M disease usage of pembrolizumab in the first line in R/M disease PD-L1 testing rate in R/M disease Description of the primary treatment approach in LA disease according to HPV status

Data analysis plan

Descriptive analysis of patient demographic, clinical characteristics and treatment patterns: minimum, maximum, median, standard deviation values for continuous variables and frequencies and percentages for categorical variables. Time to event analyses: Kaplan Meier product limit method for Time to next treatment

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

Governmental hospitals China

Data sources (types)

[Other](#)

Data sources (types), other

Data is collected from the hospitals' medical record system

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No