China Real World Study on Patient Baseline Characteristics and Treatment Pattern of Endometrial Cancer (PEC)

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48394

EU PAS number

EUPAS48393

Study ID

48394

DARWIN EU® study

No

Study countries

☐ China

Study status

Ongoing

Research institutions and networks

Institutions

Qilu Hospital of Shandong University

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Institution

First Affiliated Hospital of Xi 'an Jiaotong University Xian, China, The First Affiliated Hospital, Sun Yat-sen University Guangzhou, China, Nanjing Maternity and Child Health Care Hospital Nanjing, China, Xiangya Hospital Central South University Changsha, China, Chongqing Cancer Hospital Chongqing, China, Qingdao Central Hospital Qingdao, China, Henan Cancer Hospital Zhengzhou, China

Contact details

Study institution contact

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Primary lead investigator

Beihua Kong

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 27/10/2020

Study start date

Actual: 16/06/2021

Date of final study report

Planned: 31/10/2022

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

Main study objective:

Describe the patient characteristics and treatment patterns among newly diagnosed or recurrent endometrial cancer patients between 2015-2019: • To assess the proportion of each stage of newly diagnosed endometrial cancer • To describe treatment patterns of newly diagnosed and recurrent endometrial cancer with 6-month follow-up • To assess the demography of endometrial cancer patients

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Endometrial cancer

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

1400

Study design details

Data analysis plan

For categorical variables, the numbers of subjects, the number of non-missing observations, percentages and 95% Wilson score confidence intervals (CI) will be provided. For continuous variables, means, standard deviations, medians, upper and lower quartiles, minimums and maximums will be provided. Missing data will be assumed missing at random, no imputation method will be applied.

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

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