A single-center, prospective, observational study on the effectiveness and safety of omalizumab in Chinese patients with moderate-to-severe allergic asthma in real-world clinical settings

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Study Finalised

Administrative details

EU PAS number

EUPAS49571

Study ID

49572

DARWIN EU® study

No

Study countries

☐ China

Study status

Finalised

Research institutions and networks

Institutions

Beijing Chao-Yang Hospital, Capital Medical University

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Institution

Department of Respiratory and Critical Care Medicine

Contact details

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Primary lead investigator

Wen Wang

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 19/09/2017

Actual: 19/01/2018

Study start date
Planned: 19/12/2017

Actual: 19/03/2018

Date of final study report
Planned: 01/09/2022

Actual: 14/10/2022

Sources of funding

- Other

More details on funding

Beijing Natural Science Foundation of China

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 topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To investigate the effectiveness of omalizumab among Chinese patients with moderate-to-severe allergic asthma in a real-world clinical setting

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Single-center, prospective, observational study

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

OMALIZUMAB

Medical condition to be studied

Asthma

Population studied

Short description of the study population

The study population included patients with moderate-to-severe allergic asthma received treatment with omalizumab under real-world clinical settings in China.

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Special population of interest

Other

Special population of interest, other

Patients with allergic asthma

Estimated number of subjects

400

Study design details

Outcomes

The proportion of patients who had exacerbation during the first year following omalizumab initiation. 1. Oral or inhaled corticosteroid step-down, 2. Changes from baseline: Asthma control test, mini-AQLQ scores, forced expiratory volume in 1 second (FEV1), FeNO, and blood eosinophils.

Data analysis plan

The proportion of patients who had exacerbation will be presented as the number and percentage. The corresponding 95% CI for the proportion will be calculated using Clopper-Pearson exact method. Bowker’s test examines the statistical difference in exacerbation between pre- and post-treatment periods of one year. Secondary analyses are descriptive. Mean ACT, FEV1, FeNO, and eosinophil counts at each study visit will be calculated. A post-hoc Tukey-

Kramer HSD test will be used to perform multiple comparisons in the value between the baseline and each study visit.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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