

# 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

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### Study ID

49572

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### DARWIN EU® study

No

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### Study countries

 China

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### 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

#### Study institution contact

Wen Wang [bjchaoyanghospital@163.com](mailto:bjchaoyanghospital@163.com)

Study contact

[bjchaoyanghospital@163.com](mailto:bjchaoyanghospital@163.com)

#### Primary lead investigator

Wen Wang

## Study timelines

### **Date when funding contract was signed**

Planned: 19/09/2017

Actual: 19/01/2018

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### **Study start date**

Planned: 19/12/2017

Actual: 19/03/2018

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### **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

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### **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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**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

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## **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

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## **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.

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## **Age groups**

- Adolescents (12 to < 18 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
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## **Special population of interest**

Other

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### **Special population of interest, other**

Patients with allergic asthma

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### **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.

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### **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

## 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 sources (types)

Other

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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**Check logical consistency**

Unknown

**Data characterisation**

**Data characterisation conducted**

No