A Prospectively Observational Study to Investigate the Epidemiology and Patient Profile of Chronic Cough in Chinese Respiratory Outpatient Department

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50657

EU PAS number

EUPAS48399

Study ID

50657

DARWIN EU® study

No

Study countries

China

Study description

This is a non-interventional cross-sectional study to provide prevalence estimates for chronic cough in Chinese outpatient respiratory department. Chronic cough patients who agreed to complete surveys and questionnaires will be enrolled and used to describe patient profile, treatment patterns, patient journey and disease burden in the real-world settings in China.

Study status

Planned

Research institutions and networks

Institutions

Guangzhou Medical University

First published: 01/02/2024

Last updated: 01/02/2024

Institution

The First Affiliated Hospital

West China Hospital

First published: 01/02/2024

Last updated: 01/02/2024

Institution

China-Japan Friendship Hospital

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Institution

Tongji Hospital affiliated to Tongji Medical College of Huazhong University of Science & Technology China, Tongji Hospital of Tongji University China, West China Hospital of Sichuan University China, The First Hospital of China Medical University China, China-Japan Friendship Hospital China

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Kefang Lai

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 10/06/2022

Study start date
Planned: 31/03/2003

Date of final study report
Planned: 28/02/2024

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

Main study objective:

To investigate the disease prevalence and patient profile of chronic cough in China tertiary first-class Hospital Respiratory Outpatient Department.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Cough

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

600

Study design details

Outcomes

The prevalence of chronic cough among Chinese adult patients referring to Respiratory Outpatient Department of selected tertiary first-class hospital.

Data analysis plan

This is a non-interventional study with descriptive purposes and no statistical hypotheses testing will be performed. For the description of the sample, quantitative variables will be expressed as mean and standard deviation (SD), or median and interquartile range (IQR) where appropriate, qualitative variables will be described as frequencies or percentages, with 95% confidence intervals when necessary. Subgroup factors will include age group, gender, season and region. Subgroup analysis will use the same methodology as general

population. Any additional analysis will be documented in a separated statistical analysis plan (SAP).

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