PhEnotypic Characteristics, coMorBidities and response to thErapeutic inteRventions associated with non-type 2 asthma (EMBER)

First published: 21/10/2021

Last updated: 02/07/2024

Study Planned

Administrative details

EU PAS number

EUPAS43785

Study ID

50752

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Australia
- [ ] Bulgaria
- [ ] Canada

- [ ] Colombia
- [ ] Denmark
- [ ] Greece
- [ ] India
- [ ] Ireland
- [ ] Italy
- [ ] Japan
- [ ] Korea, Republic of
- [ ] Kuwait
- [ ] Mexico
- [ ] Portugal
- [ ] Saudi Arabia
- [ ] Spain
- [ ] Taiwan
- [ ] United Arab Emirates
- [ ] United Kingdom
- [ ] United States

Study status

Planned

Research institutions and networks

Institutions

Optimum Patient Care (OPC)

- [ ] United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Not-for-profit

Networks

Optimum Patient Care (OPC) Network

☐ United Kingdom (Northern Ireland)

First published: 26/09/2015

Last updated: 16/06/2025

Network | ENCePP partner

Respiratory Effectiveness Group (REG)

☐ Belgium
☐ Denmark
☐ France
☐ Germany
☐ Greece
☐ Hungary
☐ Italy
☐ Netherlands
☐ Spain
☐ Sweden
☐ United Kingdom

First published: 07/07/2021

Last updated: 04/06/2024

Network | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

David Price

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2021

Study start date

Planned: 01/06/2021

Data analysis start date

Planned: 01/11/2021

Date of final study report

Planned: 28/02/2023

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, OPC Global

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 describe distributions of biomarkers for patients with severe asthma, identify patients displaying evidence of non-T2 phenotype, and assess how patients with T2 and non-T2 phenotypes respond to therapeutic interventions. We additionally aim to investigate disease burden through considering comorbid diseases

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Asthma

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

11000

Study design details

Outcomes

Phenotypes of asthma patients based on biomarker measures, treatment responsiveness, exacerbation rates, Lung function, hospitalisations

Data analysis plan

Cluster analysis will be used to identify phenotypes Poisson regression and Cox PH models will be used to analyse treatment responsiveness according to phenotype Chi-square, ANOVA, and t-tests will be used as tests of association Linear and logistic regression will be used to identify differences between groups

Data management

ENCePP Seal

Composition of steering group and observers

EUPAS43785-43784.pdf(25.82 KB)

Data sources

Data source(s)

International Severe Asthma Registry

Data source(s), other

ISAR

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