EffectIveness of bioloGics (by classes) in patieNts with dIfferent combination of T2 biomarkErs (IGNITE)

First published: 25/10/2021

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS43806

Study ID

50749

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

Finalised

Research institutions and networks

Institutions

Observational & Pragmatic Research Institute Pte (OPRI)

- [ ] United Kingdom

First published: 06/10/2015

Last updated: 19/08/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | ENCePP partner

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

Actual: 01/05/2017

Study start date

Planned: 01/06/2021

Actual: 01/05/2017

Date of final study report
Planned: 14/07/2023

Actual: 27/06/2023

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, OPC Global

Study protocol

IGNITE protocol v2 15th Oct 2021.pdf(440.29 KB)

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:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To investigate whether T2 inflammatory biomarker measurements tend to be correlated within patients, and whether biomarker traits are associated with responsiveness to treatment with biologics

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Observational

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Patients aged 18 years or older diagnosed with severe asthma identified from the international severe asthma registry (ISAR) for the period of 2018 to 2021.
Inclusion Criteria:
Objective 1: All patients with sufficient biomarker information available to be included in any of the analyses.
Objective 2: All patients prescribed biologics and with relevant data available for biomarkers, biologics treatment, exacerbations, lung function and asthma control.
Objective 3: All patients prescribed biologics and with pre-biologic biomarker data for all three biomarkers, biologics treatment, and relevant outcomes information.

Exclusion Criteria:
Objectives 1, 2, and 3 :

- <18 years at the index date
- Patients treated with bronchial thermoplasty

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)

Special population of interest

Other

Special population of interest, other

Patients with severe asthma

Estimated number of subjects

11000

Study design details

Outcomes

Responsiveness to treatments with biologics, T2 biomarker measurements, Exacerbations, lung function, extent of asthma control

Data analysis plan

Objective 1 will use linear and logistic regression to identify whether it appears to be the case that biomarker values tend to be associated within the same individual Objective 2 will use generalised estimating equations to assess whether exacerbation rates appear to change over time according to biomarker values Objective 3 will use backward stepwise models to assess whether including more biomarker information significantly improves model fit Data will be described and associations tested using t-tests, ANOVA, or chi-square depending on the format of the data

Documents

Study results

IGNITE report v3 - FINAL version_[270623].pdf(5.07 MB)

Data management

ENCePP Seal

Composition of steering group and observers

EUPAS43806-43805.pdf(25.99 KB)

Data sources

Data source(s)

International Severe Asthma Registry

Data sources (types)

Disease registry

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