International Severe Asthma Registry (ISAR)

First published: 23/04/2018
Last updated: 02/07/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/47596

EU PAS number
EUPAS23651

Study ID
47596

DARWIN EU® study
No

Study countries
Australia
Bulgaria
Canada
Denmark
Estonia
Finland
France
Germany
Greece
Iceland
Italy
Japan
Korea, Republic of
Netherlands
Norway

Spain
Sweden
United Kingdom
United States

Study description
The international Severe Asthma Registry (ISAR) is a multi-country, multicentre, observational initiative to gather anonymous longitudinal real-life data, for patients with severe asthma from over 14 countries. The purpose of the registry is to provide a mechanism to store data to enable greater power to answer key research questions in severe asthma across the collaborating countries. The key feature of the International Severe Asthma Registry will be a standardised annualised recording of: • A key set of severe asthma related data points • Selected enhanced data points for optional additional data collection • Standardised coding for data point variables and • Standardised response options Due to its innovative approach with comprehensive data collection, the registry will have a core component where the key variables will be collected via eCRFs creating a large web-based registry platform in which more specific studies addressing particular objectives can be accommodated. The details of the sub-studies will be finalised and shared. The sub-studies will be conducted in subsamples of patients from the registry and the countries may choose whether or not to participate in new sub-studies without jeopardizing their status as ISAR participants. Significant changes in the protocol and new sub-studies will be reviewed by those entities prior to initiation. All patients enrolled in the ISAR platform will be followed-up annually during routine clinical visits for a total duration of up to four years.

Study status
Finalised

Research institution 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
08/08/2023
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:
01/05/2017

Actual:
15/05/2017

Study start date
Planned:
01/11/2017
Actual:
16/04/2018

Date of final study report
Planned:
01/05/2022
Actual:
14/08/2020

Sources of funding

- Other
- Pharmaceutical company and other private sector

More details on funding

AstraZeneca, OPC Global

Study protocol

OR00617_ISAR Registry Protocol_V1.2_11 April 2018.pdf(479.34 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:
Assessment of risk minimisation measure implementation or effectiveness
Disease epidemiology
Effectiveness study (incl. comparative)

Data collection methods:
Combined primary and secondary data collection

Main study objective:
Describe and characterise the severe asthma patient population natural history overall where appropriate and by different subgroups (e.g. by age, sex, etc)Facilitate the phenotyping and endotyping of patients with severe asthma and to describe these groups by the burden of illness, disease management patterns and clinical evolution in these patient populations in an international setting.

Study Design

Non-interventional study design
Other

Non-interventional study design, other
Registry Study, multi-country, multicentre, observational initiative which will retrospectively and prospectively collect data regarding severe asthma patients

Study drug and medical condition

Medical condition to be studied
Asthma

Population studied

Short description of the study population
Patients receiving care at severe asthma secondary and tertiary care centres in each participating country in accordance with local regulatory/ethical requirements.

Inclusion Criteria
• Patients 18 years or older
• Patients in receiving treatment according to GINA Step 5 or uncontrolled in Step 4. Uncontrolled is defined as having severe asthma symptoms or frequent exacerbations

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
Asthma patients

Estimated number of subjects
10000

Study design details

Data analysis plan
Describing the natural history of severe asthmaPhenotyping severe asthma sub-groupsExamining significant predictors of clinical outcomes

Data management

Data sources

Data sources (types)
Disease registry
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