Assessment of the safety of LABAs in asthma in routine care by combining healthcare databases and direct patient follow-up (ASTRO-LAB)

First published: 13/11/2012

Last updated: 29/07/2016

Study Finalised

Administrative details

EU PAS number

EUPAS3099

Study ID

14482

DARWIN EU® study

No

Study countries

France

United Kingdom

Study description

Funded by the European Commission (FP7 Research Program), ASTRO-LAB is a prospective cohort study of persistent asthma patients. ASTRO-LAB aims to provide new information about the safety of inhaled therapy in Asthma, more specifically Long-Acting β2 agonists (LABAs). To reach this objective, 3000 patients aged from 6 to 40 years, will be followed during 2 years in the UK and in France. Three sets of data will be collected : medical data (in the UK: using the THIN data, in France, using data from GPs affiliated to Academia), claims data (for France) and Patient-Reported data. The study will measure the incidence of asthma exacerbations in four different groups: LABAs only, Inhaled Corticosteroids (ICs) only, LABA and ICs in fixed-dose combinations and in distinct inhalers. The study will be also focused on adherence to therapy, to develop new measurement tools and to identify determinants.”

Study status

Finalised

Research institutions and networks

Institutions

Université Claude Bernard Lyon 1

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Kappa Santé

France

First published: 20/09/2010

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Real World Evidence Solutions, IMS Health

France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

PharmacoEpidemiology Unit (PELyon), Claude Bernard Lyon 1 University

France

First published: 27/04/2010

Last updated: 21/09/2016

Institution | Outdated | Educational Institution | ENCePP partner

Parc de Salut Mar Barcelona (PSMAR)

Spain

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Hospital/Clinic/Other health care facility

PSMAR Barcelona, SP, University of Amsterdam Amsterdam, NL, University of Nottingham Nottingham, UK, Lyon Ingenierie Projet (LIP) Lyon, FR

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Eric VAN GANSE

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/12/2011

Actual: 01/12/2011

Study start date
Planned: 31/05/2013

Actual: 29/05/2013

Data analysis start date
Planned: 02/11/2015

Actual: 01/01/2016

Date of final study report
Planned: 31/05/2016

Actual: 29/07/2016

Sources of funding

- EU institutional research programme
- Other

More details on funding

FP7 programm, Private partners, Public and SME partners

Study protocol

npjpcrm ASTROLAB 2015.pdf (904.45 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The overall objective of the project is to compare the rate of severe asthma exacerbation in children and adults treated by LABAs without ICs and with concomitant ICs with the rate amongst those treated by ICs without LABAs under the conditions of routine clinical care, after adjusting for baseline differences in severity.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(R03) DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Medical condition to be studied

Asthma

Population studied

Short description of the study population

Persistant asthma patients in France and in UK included between May 2013 and February 2015.

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)

Special population of interest

Other

Special population of interest, other

Asthma patients

Estimated number of subjects

3.000

Study design details

Outcomes

Severe Asthma exacerbation. In the Astro-lab study, the definition of severe asthma exacerbation will be the combination of patient-reported courses of oral corticosteroids for asthma, asthma-related urgent medical visits, asthma-related hospital contacts or death. Adherence, Asthma control and quality of life.

Data analysis plan

Descriptive statistics will be provided for each exposure group. In addition different types of analysis are planned : - analysis based on the 4 initial exposure groups "intention to treat"- Cohort analysis with time-dependent variables analysis- Case -crossover study approach (if applicable)- Nested case control study (if applicable)

Documents

Study results

ASTROLAB_PR3_PublishableSummary.pdf (118.37 KB)

Study publications

ASTROLAB website

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.

Composition of steering group and observers

EUPAS3099-14480.pdf (71.77 KB)

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Data source(s), other

THIN

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection, Prescription event monitoring

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