# 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.”

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**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 | 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

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**Study start date**
Planned: 31/05/2013

Actual: 29/05/2013

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**Data analysis start date**
Planned: 02/11/2015

Actual: 01/01/2016

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**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

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**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.

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**Age groups**

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

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**Special population of interest**

Other

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**Special population of interest, other**

Asthma patients

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**Estimated number of subjects**

3000

## 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.

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**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

**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