

Observational prospective cohort study to evaluate the incidence of adverse events (AE), risk factors, and drug utilization patterns related to treatment with BUSCAPINA COMPOSITUM N from March to December 2016 in patients from Metropolitan Lima (PASS PERU)

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Study

Planned

Administrative details

EU PAS number

EUPAS15008

Study ID

15009

DARWIN EU® study

No

Study countries

Peru

Study description

What AE occur in routine clinical practice, what is the incidence of AE and ADR, how many patients present with AE symptoms related to a potential liver injury. What are the drug utilization patterns in patients, what are the predisposing factors for the occurrence of adverse events and adverse drug reactions.

Study status

Planned

Research institutions and networks

Institutions

Magaly Blas

Boticas InkaFarma Lima, Mifarma Lima, Arcángel Lima, Boticas y Salud Lima, Nortfarma Lima, Seguro Social de Salud Lima, Clínica Internacional Lima, Clínica Médica Cayetano Heredia Lima, América Salud Lima, Corporación Boticas Perú Lima

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Magaly Blas

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 21/12/2015

Study start date

Planned: 05/09/2016

Data analysis start date

Planned: 12/09/2016

Date of final study report

Planned: 05/07/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim

Study protocol

[Pharmacovigilance Plan Buscapina Compositum N - Submitted document 2015DEC28.pdf](#) (224.79 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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

1.) Identify and describe the AE and adverse drug reactions (ADR) presented in patients that are undergoing treatment with BUSCAPINA COMPOSITUM N in Metropolitan Lima.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

HYOSCINE BUTYLBROMIDE

PARACETAMOL

Medical condition to be studied

Pain

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

360

Study design details

Outcomes

Occurrence of AEs in routine clinical practice in patients that are in treatment with BUSCAPINA COMPOSITUM N (when it is used according to the label indications), Incidence of AE and ADR in patients that are in treatment with BUSCAPINA COMPOSITUM N when it is used in routine clinical practice according to label indications Frequency of patients present with AE symptoms related to a potential liver injury Drug utilization patterns in patients who receive BUSCAPINA COMPOSITUM N in pharmacies, clinics and private doctor's office in Metropolitan Lima Peru

Data analysis plan

1. For the first objective of the study a descriptive statistical analysis of frequencies will be conducted for the adverse events that are discovered. 2. For the second objective of the study, If data is available the incidence rate will be calculated including in the numerator the number of cases of people who develop an adverse event, and in the denominator the sum of the different amounts of person time that each participant in the study contributes. 3. For the third objective, we will complete a descriptive statistical analysis related to the drug utilization patterns in all patients. and compare patterns between those with and without AE. 4. For the fourth objective, we will conduct a logistic regression analysis to identify risk factors (such as past medical history, concomitant illnesses, drug utilization factors of the medication, and concomitant treatments) in patients that present with AE and adverse drug reactions related to treatment with BUSCAPINA COMPOSITUM N.

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.

Data sources

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