Post-Authorisation Observational Study to Evaluate the Safety of ADASUVE® (Staccato loxapine for inhalation) in Agitated Persons in Routine Clinical Care

First published: 20/07/2016

Last updated: 16/10/2018

Study Ongoing

Administrative details

EU PAS number

EUPAS14236

Study ID

26114

DARWIN EU® study

No

Study countries

Austria

Germany

Romania

Spain

Sweden

Study description

This is a multicenter, multinational, prospective observational study conducted in Europe to evaluate the safety of ADASUVE® when used in the routine clinical setting in agitated patients.

Study status

Ongoing

Research institutions and networks

Institutions

Ferrer Internacional

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

THAIS TEIXEIRA

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/01/2014

Actual: 14/01/2014

Study start date

Planned: 01/09/2014

Actual: 16/07/2014

Date of final study report

Planned: 31/07/2020

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Ferrer Internacional SA, Alexza Pharmaceuticals, Inc

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

To assess the frequency and nature (e.g. severity) of AEs, with a primary focus on serious adverse events (SAEs) and AESIs, including respiratory events following the administration of ADASUVE® in real world settings.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective Observational Study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N05AH01) loxapine

loxapine

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Estimated number of subjects

1.500

Study design details

Outcomes

Incidence of respiratoty AESIs, including bronchospasm-related AEs, Incidence of other (non respiratory) AESIs:hypotensionExtrapyramidal symptomsNeuroleptic malignant síndrome/rhabdomyolysisseizures

Data analysis plan

Descriptive analyses will be performed. Summaries of continuous variables will include measures of central tendency (means, medians) and spread (standard deviation, range). Summaries of categorical or ordinal variables will include counts, proportions or percentages with 95% CIs. The primary safety analysis will examine the frequency and percentage of patients experiencing SAEs, AESIs (e.g. respiratory AEs) associated with ADASUVE® treatment. AEs will be characterized according to their severity and outcome. All AE verbatim terms will be recorded and coded using Medical Dictionary for Regulatory Activities (MedDRA). The AE rates will be computed for all study patients combined and also for meaningful subgroups of patients

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