A Multinational Retrospective Medical Record Review to Evaluate Utilisation Patterns of ADASUVE® (Staccato loxapine for inhalation) in Agitated Persons in Routine Clinical Care

First published: 23/01/2015

Last updated: 24/03/2015

Study Planned

Administrative details

EU PAS number

EUPAS8419

Study ID

9083

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ France

- [ ] Germany
- [ ] Romania
- [ ] Spain
- [ ] Sweden

Study description

This multicentre, multinational, observational study conducted in Europe entails retrospective review of medical records of patients receiving ADASUVE® in real world settings.

Study status

Planned

Research institutions and networks

Institutions

Alexza Pharmaceuticals

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Edwin Kamemoto

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/01/2014

Actual: 01/01/2014

Study start date

Planned: 31/03/2015

Date of final study report

Planned: 30/09/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Alexza Pharmaceuticals, Inc.

Regulatory

Was the study required by a regulatory body?

Yes

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Main study objective:

-To assess characteristics of patients in real world settings who are receiving ADASUVE® (including adherence to all aspects of SPC)-To assess characteristics of ADASUVE® prescribers, and care settings for whichADASUVE® is used in the post-authorisation period-To assess utilisation patterns for ADASUVE® (e.g. multiple doses, other medications to treat agitation, off-label use)

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

1000

Study design details

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). The drug utilisation analysis will describe number of prescriptions broken down by prescribing department / medical specialty, indication for use, patient gender, patient age, severity of agitation and respiratory disease history. In addition, the indication for use will be further categorised as: Schizophrenia, Bipolar, and Other. Summaries of categorical orordinal variables will include counts, proportions, or percentages with 95% CIs.

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)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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