Extrapyramidal symptoms in patients treated with Abilify Maintena®: Cohort study with a 2-year follow-up using European automated healthcare databases

First published: 06/10/2017

Last updated: 06/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS21056

Study ID

36996

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ Italy
- ☐ Sweden

Study description

This post-authorisation safety study (PASS) will be conducted using longitudinal automatic healthcare databases. It uses a non-comparative historical cohort design to further assess the risk of EPS-related events linked to the use of Abilify Maintena®, in routine clinical practice.All new users of Abilify Maintena® (incident users) between country-specific market entry date and the end of the inclusion period will be included in the analysis. The first observed prescription of Abilify Maintena® for a patient after market entry is called the index prescription, and the index date relates to the date of this index prescription. The crude incidence of EPS-related events and incidence per patient-month will be estimated, using the number of exposed patients with at least one EPS-related event (during treatment exposure period). In addition, an analysis on time to EPS onset will be performed using Kaplan-Meier estimator of survival function and Cox proportional hazards regression model. In addition, a Cox proportional hazards regression model will be performed to measure the effect of known risk factors described in Section 9.3.3 Other Variables on the occurrence of EPS-related event in this population.

Study status

Ongoing

Research institutions and networks

Institutions

H. Lundbeck

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Leibniz Institute for Prevention Research and Epidemiology - BIPS

☐ Germany

First published: 29/03/2010

Last updated: 26/02/2024

Institution | Not-for-profit | ENCePP partner

RTI Health Solutions (RTI-HS)

☐ France

☐ Spain

☐ Sweden

☐ United Kingdom

☐ United Kingdom (Northern Ireland)

☐ United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

Global Database Studies, IQVIA

☐ Czechia

☐ Finland

☐ Germany

☐ Slovakia

☐ Spain

First published: 17/01/2011

Last updated: 31/07/2024

Institution | Other | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Non-interventional Research Manager H. Lundbeck A/S

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 07/07/2015

Actual: 07/07/2015

Study start date
Planned: 09/10/2017

Actual: 25/11/2017

Data analysis start date
Actual: 20/08/2018

Date of final study report
Planned: 31/03/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

H. Lundbeck A/S

Study protocol

15893N_Abstract_EUPAS_register_FINAL.pdf(137.97 KB)

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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

Aims of this study are to further assess the risk of EPS-related events linked to the use of Abilify Maintena®, in routine clinical practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Abilify Maintena

Medical condition to be studied

Schizophrenia

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

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)

Special population of interest

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

1500

Study design details

Data analysis plan

In this non-comparative study, only descriptive statistics will be used. Summary statistics (mean, standard deviation, median, inter-quartile range, minimum and maximum values) will be presented for continuous variables. Counts and percentages will be presented for categorical and binary variables. In addition, an analysis on time to EPS onset will be performed using Kaplan-Meier estimator of survival function and Cox proportional hazards regression models.

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 source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Caserta claims database

German Pharmacoepidemiological Research Database

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Population-based registers

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