Post-Authorisation Safety Study Protocol Abstract

Non-interventional Cohort Study to Investigate Sertindole Prescription Management in Real-Life Practice

Sertindole

Study No.:	14290A
EU PAS Register No.:	To be assigned before data collection starts
Sponsor (MAH):	H. Lundbeck A/S (Lundbeck) 2500 Valby (Copenhagen), Denmark
Protocol edition No.:	3.1
Date of protocol edition:	12 May 2016

Title
Non-interventional Cohort Study to Investigate Sertindole Prescription Management in Real-Life Practice.

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3.1; 12 May 2016

Rationale and Background

Sertindole (SERDOLECT®) is an atypical antipsychotic indicated in Europe for the treatment of schizophrenia. Sertindole was re-launched from 2006 in all European countries except in France, UK, Italy, Slovenia and Lithuania with adjusted SmPC with regards to cardiovascular safety risks.

As part of the Risk Management Plan, the UK Medicines and Healthcare products Regulatory Agency (MHRA) requested from H. Lundbeck A/S to perform a study assessing prescriber's adherence with sertindole SmPC requirements for ECG monitoring to minimise the risk of QT interval prolongation and cardiac disorders.

This proposed non-interventional study will assess if the routine and additional risk minimisation measures (educational material and DHPC) have reached the target population of psychiatrists and resulted in prescribing behaviour in line with sertindole SmPC with regards to mandatory ECG monitoring. Study findings will inform and potentially refine risk minimisation measures for sertindole.

Research Question and Objectives
The objective of the study is to check compliance of sertindole prescribers to perform ECG monitoring in real-life practice in line with sertindole SmPC requirement.

Study Design
This is a non-interventional, multi-country, multi-site, retrospective cohort study of schizophrenia patients initiating sertindole and followed over 12 months. Data will be collected from medical chart review with one questionnaire.

Population
Patients will be recruited by psychiatrists from in- or outpatient clinics. The study will enrol 150 patients in 3 countries in order to represent different geographic regions of Europe where sertindole is being marketed: Denmark representing Northern Europe, Greece representing South-Eastern Europe and Poland representing Central Europe.

Variables
The entire data collection will be completed at a single assessment:
- Socio-demographics
- Sertindole treatment
- Clinical symptoms
- ECG monitoring
- AEs / ADRs

Data Sources

Field study with secondary data collection from investigator's medical records (medical chart review).

Study Size

The recruitment target for the study is 150 patients who received at least one prescription of sertindole and an informed consent signed. The sample size is determined to ensure an acceptable precision of the 95% confidence interval (CI) of the expected proportion of patients with an ECG measurement at a given time point. Assuming a binomial distribution, the margin error (or half the width) of the exact 95% CI confidence interval will be at most 7% for any proportion of patients ranging from 85% to 100%. These properties will hold even with a potential of 10% of missing data (i.e. only 135 patient) at a given time point.

Data Analysis

The data will be summarized descriptively. No statistical testing will be performed.

All assessment data will be summarised by time point and country using descriptive techniques. Summary statistics (mean, standard deviation, median, 1st and 3rd quartiles, minimum and maximum values) will be presented for continuous variables. Counts and percentages will be presented for categorical and binary variables.

Milestones

Planned milestones:

- Final study protocol: Q1 2016 (P-RMS final approval)
- Start of data collection: Q3 2016
- End of data collection: Q1 2017
- Final Study Report: Q4 2017