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Paliperidone Pharmacokinetic Bioequivalence Study

Managing the BE Study Challenges of an Antipsychotic LAI

Type of Study

A Pivotal, Single-Dose, Parallel-Arm, Pharmacokinetic Bioequivalence study comparing Generic to Reference Medicinal Product of Paliperidone Palmitate Prolonged-Release Injectable Suspension (25 mg) in healthy subjects

Situational Analysis

An US-based company was seeking marketing approval in the EMEA region for its Paliperidone Palmitate Prolonged-Release Injectable Suspension Formulation (25 mg)

Veeda supported the client in following services for the successful execution of the study

- Study Design & Execution
- Investigational Product Management (IMP)
- Medical Writing
- PK Blood Samples Management (Ambulatory) & Validated Method Analysis
- Volunteer Recruitment and Retention
- Biostatistics & Data Management
- Local Regulatory Applications and Dossier Submissions

Highlights of Results Delivered

290 subjects enrolled within **2** months with **2%** Average Dropout Rates

Compliance Ratio for Ambulatory Samples was about **98%**

Safety Assessment parameters assessed throughout the study as below

- Subjects throughout the study were monitored, and safety and preventive measures were ensured to minimise the risk of AEs
- Safety parameter assessments such as Medical History, Vital Signs, Clinical Examinations, Clinical Laboratory Tests , Pregnancy Tests, and ECG were conducted

Major Study Challenges & Actions

Challenges	Action Plan
Protocol & screening complexities such as maintaining ideal Haemoglobin, Absolute Neutrophil & Platelet Counts made this study more prone to screen failure	The selection of fit & ideal volunteers was ensured by Veeda's screening team, and the screening parameters were monitored continuously
This study required the collection of multiple Ambulatory Samples at various time points for 116 days	Study staff followed up with volunteers for ambulatory samples and efficient tracking of each subject's ambulatory visits was ensured
Maintaining study timeliness and efficiency	There was a high chance of screen failure in the study, which was prevented by the screening & recruitment team with the help of the study team and proper management and communication with internal & external stakeholders

Results

- The study was completed successfully within the stipulated timeline
- The AGES (EMA) regulatory inspection was completed successfully for the PK healthy study (Clinical + Bioanalytical) of Paliperidone Palmitate Prolonged-Release Injectable Suspension (25 mg)

To know more about
our Bioequivalence Study Capabilities,
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