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Bioequivalence Assessment of Iron Sucrose Injection

Analysis of Efficacy and Safety for Anaemia Management in Healthy Volunteers

Type of Study

A randomized, balanced, open label, two treatment, single period, single dose Intravenous injection, parallel bioequivalence study of Iron Sucrose Injection USP 20 mg/mL at a dose of 100 mg (5 mL x 20 mg/mL) in normal healthy adult human subjects under fasting conditions.

Molecule Overview

Iron Sucrose Injection is indicated for the treatment of Iron Deficiency Anemia (IDA) in patients with Chronic Kidney Disease (CKD).

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

- Study Design & Execution
- Volunteer Recruitment & Retention
- Investigational Product Management (IMP) & Administration
- Local Regulatory Applications & Ethics Committee Dossiers Submissions
- PK Blood Sample Management

Highlights of Results Delivered

- Enrolment rate of **66%** with **160** subjects enrolled
- **99%** Retention Rate

Safety Assessment parameters assessed throughout the study as below

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

Major Study Challenges & Actions

Challenges	Action Plan
Medication administration was conducted through a Syringe Driver device, to ensure systematic and controlled delivery of the dosage into the patient's bloodstream within a specified timeframe	Careful observation of the Syringe Driver device was maintained to prevent any potential challenges associated with dosing
Study-specific screening tests and rigorous inclusion and exclusion criteria emphasized the critical nature of the recruitment and screening process for the clinical team	The team conducted screening based on hematological and biochemical tests, ultimately enrolling 160 subjects for the study

Challenges	Action Plan
Due to complex nature of the molecule, it was essential to handle and manage the Investigational Medicinal Product (IMP) carefully before the dosing procedure	Our team adhered to storage conditions within the stability chambers and protocol requirements, alongside verifying the IMP dispensing activities

Conclusion

Within the designated timeline, the study was successfully concluded, meeting the requirements for submission to the US Food and Drug Administration (USFDA)

To know more about our Bioavailability and Bioequivalence Capabilities, mail us at info@veedacr.com

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