A Non-Interventional Post-Market Clinical Follow-up Study of Patients Transfused with Blood Components Treated with the INTERCEPT Blood System in Routine Therapeutic Use (HV6)

First published: 20/01/2023

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Study Ongoing

Administrative details

EU PAS number

EUPAS49030

Study ID

49031

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Poland

Study description

This post-market clinical follow-up study is a noninterventional, prospective, open-label, multi-center, non-controlled, non-randomized, observational study of patients transfused with pathogen reduced platelet and/or plasma components treated with the amotosalen/UVA technology (hereafter referred to as INTERCEPT Platelets and/or INTERCEPT Plasmas). Data on use of and patient outcomes associated with the use of all INTERCEPT Platelet and/or INTERCEPT Plasma components under surveillance at each site will be collected prospectively. Participating facilities will provide transfusion services and monitor transfusions based on routine standards of care and procedures. Investigators will provide data on all transfusion reactions (TRs) occurring within the first 24 hours of each INTERCEPT transfusion, and all Serious Transfusion Reactions (STRs) occurring up to 7 days after each INTERCEPT transfusion (safety monitoring period). Transfusion Reaction is defined as an adverse event that is “possibly, probably (likely), or certainly (definitely)” related to an INTERCEPT transfusion. The number of non-INTERCEPT components transfused to enrolled patients within 24 hours of a TR will also be recorded. Any TRs that are related to non-INTERCEPT components will be documented as “excluded” or “unlikely (doubtful)” in association with the INTERCEPT component. No additional data will be collected on non-INTERCEPT components.

Study status

Ongoing

Research institutions and networks

Institutions

Cerus Corporation

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Institution

ecizinisce Universität Graz Graz, Austria, Instytutem Hematologii i Transfuzjologii Warsaw, Poland

Contact details

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Study contact

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Primary lead investigator

John Pitman

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 14/11/2019

Actual: 14/11/2019

Study start date
Planned: 01/12/2019

Actual: 01/12/2019

Date of final study report
Planned: 01/12/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Cerus Corporation

Study protocol

CLI-HV6 00138 v3.0.pdf (553.3 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

CLI-HV 00138

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The primary objective of this non-interventional post-market clinical follow-up study is to proactively collect safety data from a wide-variety of patients (male, female, all ages) transfused with INTERCEPT Platelet and INTERCEPT Plasma components in routine therapeutic use.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Hemovigilance

Study drug and medical condition

Medicinal product name, other

INTERCEPT Blood System

Population studied

Age groups

- Adolescents (12 to < 18 years)
- Children (2 to < 12 years)
- Infants and toddlers (28 days – 23 months)
- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- 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

500

Study design details

Outcomes

Proportions of patients and transfusions with TRs and STRs assessed as possibly, probably (likely), or certainly (definitely) related to the transfusion of INTERCEPT Platelet or INTERCEPT Plasma components.

Data analysis plan

Data will be summarized descriptively, by component type (platelet or plasma), by site and across all sites, without formal hypothesis testing. A 95% confidence interval for the binary endpoints (e.g. proportion of patients with any TRs) will be provided for each type of study product. Data analysis will be performed on a per patient and per-transfusion basis. Subgroup analysis by age group and sex will also be presented if subgroups contain sufficient numbers of patients. TRs and STRs may also be summarized based on their temporal relationship with the transfusion of non-INTERCEPT products.

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)

Other

Data sources (types), other

Prospective patient-based data collection, Blood bank databases are used to complement patient-based data stored in electronic medical records at each participating study site.

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