Study of INTERCEPT in Regions at Potential Risk for Zika Virus Tranfusion-Transmitted Infections

Status: OPEN TO ACCRUAL

Eligibility Criteria

Age: 4 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Stage A:

Inclusion Criteria:

• Age ? 4 years.

• Patients who require or are expected to require a transfusion of RBC component(s), including red cell exchange transfusion

• Signed and dated informed consent form.

• Female patients of child-bearing potential must:

• Have negative serum or urine pregnancy tests prior to study treatment to rule out pregnancy, and

• Agree to use to use at least one method of birth control that results in a low failure rate (i.e., less than 1% per year) when used consistently and correctly such as implants, injectables, combined oral contraceptives, some intrauterine devices (IUDs), sexual abstinence or vasectomized partner for the duration of study participation and an additional 28 days. For 28-day +6-month extension study in chronically transfused patients: ? A diagnosis of a bone marrow failure syndrome requiring repeated RBC transfusion for congenital or acquired chronic anemia (e.g., sickle cell anemia, thalassemia, other hemoglobinopathies, myelodysplastic syndrome, aplastic anemia, chemotherapy or stem cell transplant etc.) For 28-day +6-month extension study in SCD patients requiring regular repeated RCE.

• Diagnosis of SCD, either HbSS, HbSC or HbSB0 thalassemia, confirmed by Hb electrophoresis, deoxyribonucleic acid (DNA) analysis or high-performance liquid chromatography (HPLC)

• Currently participating in an automated RCE transfusion program (for at least 3 months prior to enrollment) with 3-to-8 week intervals between RCE transfusion episodes Stage A: Exclusion Criteria

• Confirmed positive baseline serum/plasma antibody specific to IBS RBC (S 303 treated RBC) as determined by INTERCEPT S 303 antibody screening panel prior to receiving the first study transfusion

• Pregnant or breast feeding.

• Presence of an RBC warm autoantibody with evidence of active hemolysis.

• Positive DAT as defined below:

• A polyspecific-DAT reaction strength > 2+, or

• A polyspecific-DAT (any strength) in conjunction with pan-reactivity with a commercial IAT antibody screening panel that precludes the identification of underlying alloantibodies or indicates the presence of autoantibody.

• Have had an RBC transfusion within 7 days prior to randomization.

• Have received investigational products, including investigational blood products, pharmacologic agents or imaging materials, within 28 days prior to randomization. Prior receipt of conventional blood products tested with an investigational NAT test is not considered ground for exclusion.

• Patients presenting with or expected to have massive hemorrhage (?10 RBC units within 24 hours) or expected to require massive transfusion protocols. Planned red cell exchange does not apply.

• Patients who require neonatal transfusions and intrauterine transfusions.

• Pre-existing antibody to RBC antigens that may make the provision of compatible study RBC components difficult.

• History of transfusion reactions requiring washed RBCs, volume reduced RBC, or RBCs with additive solution removed.

• Patients with documented IgA deficiency or a history of severe allergic reactions to blood products.

• For SCD patients to be enrolled into the repeated RCE 28-day +6-month arm of the study:

• A history of acute chest syndrome in the last 6 months, or hyperhemolysis syndrome at any time.

• Clinical evidence of splenic hyperfunction or splenic enlargement: ?18 cm in longitudinal diameter (diagnosed at the Investigator's discretion according to the data available, with ultrasound data being preferable).

• Currently receiving chemotherapy for treatment of cancer. Hydroxyurea for SCD is acceptable if subject has been on stable therapy for 3 months and no changes to dosage are planned.

• Subject is in active treatment with renal dialysis.

• Any subject for whom a substantial change in the number of RBC components transfused is anticipated due to anticipated splenectomy, bone marrow transplant, surgery or other change in clinical status.

• Subject with known G6PD deficiency or requiring treatment with medications that are known to adversely affect RBC viability or bone marrow function.

Conditions & Interventions

Interventions:

Device: INTERCEPT Blood System for Red Blood Cells, Device: Conventional (Control)

Conditions:

Anemia

Keywords:

INTERCEPT, Red Blood Cells, RBC, Pathogen Inactivation, Zika, Cerus, Pathogen Reduction

More Information

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Phase: III

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System ID: NCT03037164

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