Ebola Convalescent Plasma Trial in West Africa

Clinical Trial Sponsor: Clinical Research Management, Inc. (ClinicalRM)

Presented for IPFA, May 2015
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Blood Centers of America, Inc.
Purpose (Protocol 1)

Correlate IgG and neutralization titers in Ebola Convalescent Plasma with viral load in treated subjects

Compare survival of subjects treated with and without plasma

Assess safety of treatment with and without plasma
Purpose (Protocol 2)

Pre-qualify potential Ebola Convalescent Plasma donors for donation and collect plasma by apheresis for clinical trials or compassionate use

Assess quantitative and qualitative changes in anti-Ebola virus antibody in survivors over a period of one year
EBOLA IS SERIOUS
EBOLA IS A VIRUS

DO NOT EAT BUSH MEATS

HOW IT IS SPREAD FROM PERSON TO PERSON:
• Contact with Bodily Fluid from an Infected Person
  • Do Not Touch
  • Do Not Shake Hands or Hug

HOW TO PREVENT THE SPREAD OF EBOLA:
GLOVES • EYE PROTECTION
GOWNS • MASKS • BLEACH
ANTIBACTERIAL SOAP
DISINFECTANT SPRAY
HAND SANITIZERS

SYMPTOMS OF EBOLA:
• VOMITING
• DIARRHEA
• BLEEDING
Who?

**Clinical Trial Sponsor:** ClinicalRM

**Funding provided by:** Bill & Melinda Gates Foundation

**Subject matter experts contracted from:**
- SIM and ELWA Hospital: Dr. Jerry Brown, PI
- University of North Carolina; Duke University
- Safe Blood for Africa
- Blood Centers of America, Inc.

**Virologic and immunologic analyses provided by:** USAMRIID

All clinical work was performed by Liberians
Who? (continued)

HopeMobile: Paul Allen Foundation and the Jim Greenbaum Foundation

Transportation of equipment provided by: World Food Programme

INTERCEPT for PI: Cerus Corp.

Apheresis equipment: Haemonetics

Protocols approved by: Liberian and US IRBs
Oversight by: Multinational DSMB
Operational Objectives (Protocol 2)

Deploy outfitted bloodmobile for donor screening, plasma collection, pathogen inactivation

Develop SOPs and Train Staff

Configure and Implement BECS

Develop Processes around handling plasma; freezing, pairing, thawing, distributing

Collect Convalescent plasma from Ebola Survivors
Meeting the HopeMobile
November 15
Inside the HopeMobile
Inventory – 3 days in a metal box
Training – PCS2 Collections
Pathogen Inactivation
The Apheresis/Laboratory Team

Darlington Komosee    Galakpai Gorvego    Uriah Glaybo
Survivors = Donors

On discharge, contact information collected

Survivors provided with certificates

Survivors provided with basic replacement items
- Mattresses
- Clothing
- Etc.
Donor Recruitment

Compensation for Time and Travel

Transportation

Verification of Survivor Status

Health Symposia/Clincs

Empowerment/Survivor Groups
Donor Protocol

Screen donors with questionnaire

Collect 650ml plasma/samples for IDT

Pathogen Inactivation

Split into 100ml bags

Freeze/Label/Store

IDT using rapid antibody detection tests
## Donor Suitability
*(first 67 screened donors; 58 collected)*

<table>
<thead>
<tr>
<th>Concerns</th>
<th>Reality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Metabolic Status</td>
<td>Only 3 women “in their moon” were deferred for Hgb &lt; 12.0</td>
</tr>
<tr>
<td>Low Hemoglobin</td>
<td>No deferrals for weight</td>
</tr>
<tr>
<td>Low Weight</td>
<td>16 donors permanently deferred (24%)</td>
</tr>
<tr>
<td>High Infectious Disease Rate</td>
<td>No reactions/8 QNS (14%)</td>
</tr>
<tr>
<td>High Reaction Rate</td>
<td>Currently unable to test for protein</td>
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<tr>
<td>Low Total Protein/Albumin</td>
<td></td>
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</table>
Our First Donor

December 5 – Screening Visit
23yo, female; 52kg

Infected with Malaria on discharge from ETU

Donated Convalescent WB previously

Scared of needles

December 8 - Donation
Donor Care

Each offered meal in Cafeteria

Ca+ fortified water during screening

Screened for orthostatic (postural) drop in BP

500 ml Saline replacement end of procedure

Standard snacks on discharge

Multivitamins/Iron given as part of their Screening “Thank You” package

EMLA cream

Strong Donor Engagement throughout process
Patient Transfusions
(1st Protocol)
Protocol Particulars

Assumption that Plasma Availability would be limiting factor

Each patient receives 3 treatments 48 hr apart
- 2, 100ml bags
- 2 donors paired
- Patient gets all plasma from same 2 donors

Allows for A to go to B

EBOV tested in recipients at consent and before and after each txn
6 Patients Enrolled

- Monitored with ISTAT – Chem8+ and INR
- Generally high BUN/creatinine
- 4 Opos (transfused)
- 2 Apos (control group)
  NO Apos plasma available

(Stored plasma is 70% Opos, 20% Bpos, 10% Apos)

- Currently no Patients in Liberia to enroll
Ongoing Work

Stockpiling plasma for future need
Collecting data/samples on Survivors
Exploring partnership for IG fractionation