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Convalescent plasma for early Ebola virus disease in Sierra Leone

Submission date
20/04/2015

Recruitment status
No longer recruiting

Registration date
27/04/2015

Overall study status
Completed

Last Edited
17/05/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Ebola virus disease is a severe, often fatal illness which is caught by direct contact with an infected persons blood, secretions, organs or other bodily fluids and from materials (such as bedding) contaminated with these fluids. Early symptoms of infection include flu-like symptoms and fever, headache and intense muscle weakness. Stomach pain, vomiting, diarrhoea then follows and liver and kidney function is also affected. Finally, there is internal bleeding, with blood often seen to bleed from the ears, eyes, nose and mouth. The infection is fatal in between 50-90% of cases. There is not, as present, any licensed treatment or vaccine for Ebola virus disease. However, there are a range of potential treatments including blood products, immune therapies and drug therapies being tested. Here, we want to rapidly assess how well convalescent plasma (CP), that is plasma from survivors of the Ebola virus, works as a treatment for the condition and safe it is to give to patients.

Who can participate?
People of any age admitted to a Ebola treatment unit and diagnosed with the virus and also health care workers who have been placed at risk of being infected. Survivors of Ebola virus are invited to donate their plasma for treatment.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (intervention) are given a single transfusion of CP. Those in group 2 (control) are given the same amount of Ringer' s Lactate solution. Patients in both groups are also given the usual standard of care (SC). All cause mortality (causes of death) is then investigated 14 days after the treatment for both groups.

What are the possible benefits and risks of participating?
Patients who are given the CP may have a better chance of surviving Ebola. However, they do risk having a reaction to the CP. There are no benefit to donors, other than they are given a health care assessment. Risks include bruising from the venepuncture when donating CP. Donors have their plasma replaced with saline so are not as risk of hypovolaemia (low blood volume) which could cause faintness. The greatest risk is to the healthcare workers who administer the treatment as they may become exposed to the Ebola virus.

Where is the study run from?
Ebola Treatment Unit, Freetown (Sierra Leone)

When is the study starting and how long is it expected to run for?
November 2014 to February 2016

Who is funding the study?
Wellcome Trust (grant number 106491/Z/14/Z0)

Who is the main contact?
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Contact information

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Additional identifiers

Protocol serial number
Protocol number: MOHS-CST001; Pan African Clinical Trials Registry number: PACTR201602001355272

Study information

Scientific Title
Convalescent plasma for early Ebola virus disease in Sierra Leone: an open-label, non-randomized, controlled clinical trial

Acronym
Ebola_CP

Study objectives
That transfusion of a single unit of convalescent plasma in early Ebola virus disease reduces absolute mortality by 20%

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sierra Leone Ethics and Scientific Review Committee, Ministry of Health and Sanitation, V0.3, 16 /12/2014, V0.4, 07/02/2015, V0.5, 19/03/2015, ref: PBSL/CTAN/MOHS-CST001-15-002

Primary study design
Interventional

Study design
Emergency pragmatic phase 2/3 open-label non-randomized, controlled clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Early Ebola virus disease

Interventions
1. Active Arm: A single transfusion of convalescent plasma from Ebola virus disease survivors
2. Control Arm: A single intravenous bolus of Ringer's Lactate

Intervention Type
Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Ebola Convalescent Donor Plasma (un-fractionated)

Primary outcome(s)
All cause mortality at day 14 post intervention

Key secondary outcome(s)
1. To compare 30 day all cause survival on CP+SC to SC+RL/0.9% saline
2. To assess the relationship between EV antibody levels in donated CP and survival
3. To assess the relationship between EV antibody levels in donated CP and changes in levels of viral RNA in the blood of patients over time
4. To assess the occurrence of serious adverse reactions (SARs) related to CP transfusion or RL/0.9% saline infusion in patients
5. To assess the occurrence of safety risks related to CP transfusion or RL/0.9% saline infusion in health workers administering the treatments
6. To determine risk factors for mortality despite administration of CP (for identification of patients most likely to benefit)
7. To determine risk factor for mortality at day 14 and day 30

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Persons of all ages and sex admitted to Ebola treatment units with confirmed Ebola virus disease
2. Health care workers who experience a safety incident as a result of the intervention
3. Survivors of Ebola virus disease who volunteer to donate plasma

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
1. Those for whom the intervention is contraindicated
2. Those who are unresponsive (per AVPU) just prior to intervention
3. Those for whom any intervention is considered futile

Date of first enrolment
19/03/2015

Date of final enrolment
29/02/2016

Locations

Countries of recruitment
Sierra Leone

Study participating centre
Ebola Treatment Unit
34th Regiment Military Hospital
Wilberforce Barracks
Freetown
Sierra Leone
-

Study participating centre
Blood Service
Connaught Hospital
Tower Hill
Freetown
Sierra Leone
-

Sponsor information

Organisation
University of Liverpool

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust (grant number: 106491/Z/14/Z0)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	article on feasibility of donor recruitment	01/05/2018	01/08/2019	Yes	No
Other publications		27/01/2021	17/05/2023	Yes	No