

Convalescent plasma for early Ebola virus disease in Sierra Leone

Submission date 20/04/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/04/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 17/05/2023	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

Study design

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

Primary study design

Interventional

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

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Study participating centre**Blood Service**

Connaught Hospital

Tower Hill

Freetown

Sierra Leone

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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