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Interferon-β treatment for Ebola virus disease

Submission date	Recruitment status	[_] Prospectively registered
14/07/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/07/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/03/2019	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Ebola virus disease is a serious illness caused by the Ebola virus. The virus originated in Africa and is particularly common in West Africa, where there is currently a serious outbreak. A person infected with Ebola will usually develop a fever, headache and muscle pain/weakness, but if left untreated, it could lead to serious gastrointestinal (gut) symptoms, impaired kidney and live function, internal bleeding and even death. To date, there are no approved drugs for the treatment of Ebola virus disease. Interferon-β (interferon-beta) is a broad spectrum (general) antiviral medication that has shown limited activity against the Ebola virus in laboratory experiments on cells and animals. Given the severity of the Ebola outbreak in West Africa, a study has been designed to test Interferon-β on people with Ebola virus disease in Guinea (West Africa). The aim of this study is to evaluate the safety and effectiveness of Interferon-β in the treatment of patients with Ebola virus disease.

Who can participate?
Adults with Ebola virus disease, who are being treated in the Coyah Ebola Treatment Unit (Guinea).

What does the study involve?
After agreeing to take part, participants receive an injection of Interferon-β under the skin every day for up to 10 days. During this time, patients also receive standard treatment including receiving fluids, pain and fever medication, vitamins, anti-sickness tablets and antibiotics. Participants have a sample of blood taken at the start of the study and then after 2, 4, 6, 9, 11, 13 and 15 days to test the level of the virus present in the body. Participants are also monitored in order to record any negative side effects they get from the medication.

What are the possible benefits and risks of participating?
There is a chance than participants may benefit from a better recovery form Ebola virus disease because of the Interferon-β treatment. The risks associated with this treatment are not known in the treatment of Ebola virus disease but patients will be closely monitored for side effects. There is also a risk of pain or bruising from the blood testing.

Where is the study run from?
Coyah Ebola Treatment Unit (Guinea)

When is the study starting and how long is it expected to run for?
March 2015 to December 2016

Who is funding the study?
Canadian Institutes of Health Research (Canada)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2014-EBOV

Study information

Scientific Title
A pilot study to evaluate the safety and efficacy of interferon beta-1a (IFN β-1a) in the treatment of patients presenting with Ebola virus illness

Study objectives
IFN β-1a treatment is an effective treatment for Ebola virus disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Guinean Comite National D'Ethique pour la Recherche en Sante (CNERS), ref: 016/CNERS/15

Study design
Single-centre single-arm phase I/II non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Acute ebola virus disease

Interventions
All participants receive subcutaneous injection of 30µg (6 x 10v6 IU) IFN β-1a daily for up to 10 days, until two consecutive PCR CT values for ebola viremia in blood were >40 (ie virus undetectable), 48 hours apart. Patients that are PCR negative for blood viremia are discharged from the Coyah Treatment Unit after the second negative PCR value, having resolved all clinical symptoms of Ebola virus disease.

Patients also recieve standardized supportive care throughout, including rehydration solution, pain and fever medication (Novalgin, Paracetamol), Plumpy'Nut therapeutic diet, vitamin B complex, multivitamins, oral Omerprazole or intravenous Metoclopramide, cephalosporin antibiotics Cefixme (oral) and Ceftriaxone (intravenous), antibiotic Metronidazole, and the anti-malarial, Coartem.

Participants are followed up at 2, 4 , 6, 9, 11, 13 and 15 days.

Intervention Type
Biological/Vaccine

Phase
Phase I/II

Primary outcome measure
Viral load reduction/clearance from the blood is determine using a semi-quantitative RT-PCR assay at baseline, 2, 4 , 6, 9, 11, 13 and 15 days.

Secondary outcome measures

1. Safety of IFN β-1a treatment is determined by monitoring for any adverse events daily for the time period each patient is in the treatment unit
2. Occurrence, nature and severity of adverse events events are determined by the clinical team and attending MD at the Coyah Treatment Unit daily for the time period each patient is in the treatment unit

Overall study start date
22/09/2014

Completion date
19/04/2016

Eligibility

Key inclusion criteria
1. Able to provide informed consent (ubstitute decision maker may provide informed consent in cases where the patient is ill and unable to provide informed consent)
2. Aged between 18 and 70 years on the day of inclusion
3. In the treatment centre
4. Confirmed ebola virus infection by RT-PCR
5. Symptom onset < 6 days
6. Able to comply with trial procedures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
30-50

Key exclusion criteria
1. Known hypersensitivity to IFN β preparations
2. Pregnancy
3. Chronic liver disease with synthetic dysfunction and/or decompensation, history of bleeding
4. Moderate to severe congestive heart failure - grade III or IV left ventricular function
5. Previous history of serious psychiatric illness
6. History of sever or active autoimmune disease

Date of first enrolment
26/03/2015

Date of final enrolment

12/06/2015

Locations

Countries of recruitment
Guinea

Study participating centre
Coyah Ebola Treatment Unit
Coyah
Guinea
-

Sponsor information

Organisation
Sustainable health Foundation (FOSAD) & Center of Excellence for Training on Research and Priority Diseases (CEFORPAG)

Sponsor details
Nongo Commune Ratoma
Conakry
Guinea
-

Sponsor type
Research organisation

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Planned publication of data acquired in a peer-reviewed scientific journal.

Intention to publish date
01/07/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/02/2017	01/03/2019	Yes	No