

Interferon- β treatment for Ebola virus disease

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| Submission date 14/07/2016 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 19/07/2016 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 01/03/2019 | Condition category Infections and Infestations | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

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 liver 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 that participants may benefit from a better recovery from 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

Protocol serial number
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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Acute ebola virus disease

Interventions

All participants receive subcutaneous injection of 30 μ g (6 x 10⁶ 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 receive standardized supportive care throughout, including rehydration solution, pain and fever medication (Novalgin, Paracetamol), Plumpy'Nut therapeutic diet, vitamin B complex, multivitamins, oral Omeprazole or intravenous Metoclopramide, cephalosporin antibiotics Cefixime (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(s)

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

Key secondary outcome(s)

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 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

Completion date

19/04/2016

Eligibility

Key inclusion criteria

1. Able to provide informed consent (substitute 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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

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Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

Canadian Institutes of Health Research

Alternative Name(s)

Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

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 |