

# Highly Active Antiretroviral Treatment (HAART) of Human Immunodeficiency Virus (HIV)-infection in a town in Cameroon: randomised controlled study to suggest which treatment starting point is most beneficial for the patients

**Submission date**  
29/06/2007

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
06/07/2007

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
03/08/2015

**Condition category**  
Infections and Infestations

☐ Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

### **Scientific Title**

Highly Active Antiretroviral Treatment (HAART) of Human Immunodeficiency Virus (HIV)-infection in a town in Cameroon: randomised controlled study to suggest which treatment starting point is most beneficial for the patients

### **Acronym**

CD4 RCT

### **Study objectives**

Null hypothesis: no difference on outcome (corrected for lead bias) if treatment starts at CD4 levels 250 or 350 cells/mm<sup>3</sup> in World Health Organisation (WHO) clinical stage 1 - 2 patients.

On 17/09/2008 the overall trial end date was changed from 31/12/2008 to 31/12/2010.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

1. Regional Medical Research Ethics Committee in Western Norway (REK VEST), 26/06/2002, ref: 115/02
2. In Cameroon: Oral approval from local health authorities

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

HIV infection

### **Interventions**

Each participant will be randomised to one of the following groups:

Group 1: HAART starting at CD4 levels 250 cells/mm<sup>3</sup>

Group 2: HAART starting at CD4 levels 350 cells/mm<sup>3</sup>

### **Intervention Type**

Drug

### **Phase**

Not Applicable

### **Drug/device/biological/vaccine name(s)**

Highly Active Antiretroviral Treatment (HAART)

### **Primary outcome measure**

1. WHO clinical stage, assessed after one and possibly also after two years of treatment
2. Changes in CD4 count after randomisation and after start of treatment

### **Secondary outcome measures**

1. Weight maintenance
2. Intercurrent diseases
3. Acquired Immune Deficiency Syndrome (AIDS) development
4. Survival

### **Overall study start date**

01/07/2007

### **Completion date**

31/12/2010

## **Eligibility**

### **Key inclusion criteria**

1. Treatment naive Human Immunodeficiency Virus (HIV)-infected individuals
2. 16 years of age or older
3. CD4 count between 450 and 250 cells/mm<sup>3</sup>

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

100

### **Key exclusion criteria**

1. If patient fulfils current indications for immediate treatment: CD4 less than 250 cells/mm<sup>3</sup> or WHO clinical stage 3 or 4
2. If CD4 is currently greater than 450 cells/mm<sup>3</sup> . This is because patient will probably not start Anti-Retroviral Therapy (ART) during the first year to come

**Date of first enrolment**

01/07/2007

**Date of final enrolment**

31/12/2010

## Locations

**Countries of recruitment**

Cameroon

Norway

**Study participating centre**

University of Tromsø

Tromsø

Norway

9012

## Sponsor information

**Organisation**

Institute of Community Medicine, University of Tromsø (Norway)

**Sponsor details**

Breivika

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Norway

9037

+47 77644000

anne.fismen@ism.uit.no

**Sponsor type**

University/education

**Website**

<http://uit.no/samfmed/>

ROR

<https://ror.org/00wge5k78>

## Funder(s)

### Funder type

University/education

### Funder Name

Institute of Community Medicine, University of Tromso (Norway)

### Funder Name

Norwegian Global Health Program (Norway)

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### 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?
<a href="#">Results article</a>	results	10/08/2014		Yes	No