ISRCTN22114173 https://doi.org/10.1186/ISRCTN22114173

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

Registration date
06/07/2007

Overall study status
Completed

Last Edited
03/08/2015

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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^3 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

Study type(s)
Treatment

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^3
Group 2: HAART starting at CD4 levels 350 cells/mm^3

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Highly Active Antiretroviral Treatment (HAART)

Primary outcome(s)
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

Key secondary outcome(s))
1. Weight maintenanace
2. Intercurrent diseases
3. Acquired Immune Deficiency Syndrome (AIDS) development
4. Survival

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^3

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. If patient fulfils current indications for immediate treatment: CD4 less than 250 cells/mm^3 or WHO clinical stage 3 or 4
2. If CD4 is currently greater than 450 cells/mm^3 . 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
Tromsoe
Norway
9012

Sponsor information

Organisation
Institute of Community Medicine, University of Tromsø (Norway)

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

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?
Results article	results	10/08/2014		Yes	No