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A randomised, triple-arm study to compare the viral and immunological outcome of highly active anti-retroviral therapy during six versus 15 months versus no treatment in patients with primary human immunodeficiency virus-1 (HIV 1) infection

Submission date
23/02/2007

Recruitment status
No longer recruiting

Registration date
23/02/2007

Overall study status
Completed

Last Edited
16/01/2019

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

Contact name
Prof Dr. J.M. Prins

Contact details
Academic Medical Centre (AMC)
University of Amsterdam
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ
+31 (0)20 566 4380
j.m.prins@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR101

Study information

Scientific Title
A randomised, triple-arm study to compare the viral and immunological outcome of highly active anti-retroviral therapy during six versus 15 months versus no treatment in patients with primary human immunodeficiency virus-1 (HIV 1) infection

Acronym
Primo-SHM

Study objectives
The aim of this study is to provide data on the effect of treatment during primary human immunodeficiency virus infection (PHI) on the viral set-point and the optimal duration of such treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the AMC Medical Ethics Committee (ref: MEC 03/059).

Study design
Randomised, active controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV), primary human immunodeficiency virus-1 (HIV-1) infection

Interventions

Six or 15 months of highly-active anti-retroviral therapy (HAART) initiated during primary HIV-1 infection.

As of 11/08/2010 the status of this record is that inclusion to the trial has stopped and follow-up is ongoing.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Highly active anti-retroviral therapy (HAART)

Primary outcome measure
Plasma HIV-1 RNA at week 96:
1. Magnitude of viral set-point will be evaluated for both treatment groups 36 weeks after treatment discontinuation, and a comparison will be made between all groups at week 96 (= study end)
2. Comparison between all three groups of viral kinetics (including rebound) during the off-treatment periods

Secondary outcome measures
1. CD4+ cell counts
2. Safety: (serious) adverse events, HIV related events and death
3. Quality of life
4. Time between diagnosis and start/reinitiation of HAART
5. Time between treatment discontinuation and reinitiation of HAART

In selected groups/individuals:
6. HIV-1 specific CD4+ and CD8+ T-cell response and their state of activation and maturation
7. Humoral immune response parameters

Overall study start date
01/05/2003

Completion date
01/02/2012

Eligibility

Key inclusion criteria
Diagnosis of acute/recent human immunodeficiency virus-1 (HIV-1) infection: plasma HIV-1 ribonucleic acid (RNA) load detectable and/or detectable serum p24 antigen and one of the following:
1. Enzyme-linked immunosorbent assay (ELISA): HIV-1 specific antibodies negative, or
2. ELISA: low level antibodies or HIV-1 specific antibodies positive and a negative, incomplete or indeterminate Western Blot (antibodies against a maximum of three of the HIV specific proteins), or

3. ELISA: HIV-1 specific antibodies positive and positive Western Blot, but with documented negative HIV-1 ELISA in the preceding 180 days

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
173

Key exclusion criteria
Does not comply with the above inclusion criteria

Date of first enrolment
01/05/2003

Date of final enrolment
01/02/2012

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre (AMC)
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (The Netherlands)

Sponsor details

University of Amsterdam
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
Hospital/treatment centre

Website
http://www.amc.uva.nl

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Government

Funder Name
Dutch Government (The Netherlands)

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?
Results article	results	01/09/2012	16/01/2019	Yes	No