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The SPARTAC trial: a multicentre randomised trial of therapeutic intervention at primary human infection immunodeficiency virus-1 (HIV-1) infection

Submission date
22/07/2005

Recruitment status
No longer recruiting

Registration date
22/07/2005

Overall study status
Completed

Last Edited
24/02/2015

Condition category
Infections and Infestations

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

Plain English summary of protocol
http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=32

Study website
http://www.imperial.ac.uk/departmentofmedicine/divisions/infectiousdiseases/infectious_diseases/hiv_trials/hiv_treatment/spartac

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2004-000446-20

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
069598

Study information

Scientific Title
Short Pulse AntiRetroviral Therapy At human infection immunodeficiency virus (HIV) seroConversion: a Multicentre randomised trial of therapeutic intervention at primary HIV-1 infection

Acronym
SPARTAC

Study objectives
The study is a randomised controlled trial comparing three different strategies of intervention in Primary Human Immunodeficiency Virus (HIV) Infection (PHI). The primary objective is to determine the effect of two anti-HIV treatment schedules of limited duration in PHI on the rate of CD4 decline and, consequently, on the time to initiating long-term anti-HIV therapy. The secondary objective is to evaluate the effect of different durations of treatment during PHI on HIV-specific immune response and disease progression. The aim of early antiretroviral intervention is to preserve HIV-specific CD4+ T-cell responses from HIV-induced lysis in order to confer enhanced control of viral replication when therapy is subsequently discontinued.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The London Multicentre Research Ethics Committee (MREC), 29/07/2004, ref: 04/2/025

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact clinical.researchoffice@imperial.ac.uk to request a patient information sheet

Health condition(s) or problem(s) studied
Human immunodeficiency virus (HIV)

Interventions
Participants will be randomly allocated in a 1:1:1 ratio at trial entry to start one of the regimens of open treatment with:
Arm A: Long course Combination AntiRetroviral Therapy (LCART) for 48 weeks
Arm B: Short course Combination AntiRetroviral Therapy (SCART) for 12 weeks
Arm C: No antiretroviral therapy

The regimen should be started, ideally, on the day of randomisation, or within 72 hours.

Intervention Type
Drug

Phase
Not Applicable

Primary outcome measure
Time to CD4 cell count less than 350 cells/l (excluding counts in the first three months after diagnosis) on two consecutive occasions not more than four weeks apart. Intervention at PHI is termed PTX (primary treatment) to distinguish it from late treatment (LTX), which may be administered according to local HIV treatment guidelines when indicated.

Secondary outcome measures
1. HIV-specific CD4+ and CD8+ T-cell responses at week 60
2. Slope of CD4 decline
3. Time from randomisation to virological failure of first regimen of late treatment (LTX) or death
4. Development of drug resistance not present at baseline, before starting LTX or at week 120 whichever is earlier
5. Development of an AutoImmune Deficiency Syndrome (AIDS) defining illness or death
6. Time from randomisation to the initiation of late treatment (LTX)
7. Differences in blood pressure from randomisation at week 12 and week 48

Overall study start date
01/11/2004

Completion date
30/01/2009

Eligibility

Key inclusion criteria
Patients of both sexes will be eligible for screening if they:
1. Have reached the age of consent in their country for participating in a clinical study
2. Are confirmed PHI by at least one of following criteria:

2.1. HIV positive antibody test within six-months of an HIV negative antibody test (randomisation must take place within six months of previous negative test)
2.2. HIV antibody negative with positive Reverse Transcription Polymerase Chain Reaction (RT-PCR)
2.3. Test 'incident' at low level (less than 0.6) using detuned assay (must be subtype B)
2.4. Equivocal HIV antibody test supported by a repeat test within a two-week period showing a rising optical density
2.5. Have clinical manifestations of symptomatic HIV seroconversion illness supported by antigen positivity and less than four bands positive on Western Blot
3. Able and willing to give written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
360

Key exclusion criteria
Patients will not be eligible for screening if:
1. Pregnant
2. Unlikely to comply with protocol, and in particular adhere to therapeutic regimen
3. Likely to use narcotics during the study period
4. Antiretroviral therapy is indicated
5. Antiretroviral therapy is contraindicated

Date of first enrolment
01/11/2004

Date of final enrolment
30/05/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College of Sci Tech & Med
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Sponsor information

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Imperial College London (UK)

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Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

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	17/01/2013		Yes	No
Results article	results	25/10/2013		Yes	No
Results article	results	13/03/2014		Yes	No