

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

<b>Submission date</b> 22/07/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 22/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/02/2015	<b>Condition category</b> 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

[http://www.ctu.mrc.ac.uk/research\\_areas/study\\_details.aspx?s=32](http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=32)

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2004-000446-20

### Protocol serial number

## 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

### Primary study design

Interventional

### Study design

Multicentre randomised controlled trial

### Study type(s)

Treatment

### 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(s)**

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.

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**Study participating centre**

Imperial College of Sci Tech & Med

London

United Kingdom

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**Sponsor information****Organisation**

Imperial College London (UK)

**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

**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	17/01/2013		Yes	No
<a href="#">Results article</a>	results	25/10/2013		Yes	No
<a href="#">Results article</a>	results	13/03/2014		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes