

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	<input type="checkbox"/> Prospectively registered
Registration date 22/07/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/02/2015	Condition category 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

Study website

http://www.imperial.ac.uk/departmentsofmedicine/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

London

United Kingdom

W2 1PG

Sponsor information

Organisation

Imperial College London (UK)

Sponsor details

Level 2, Faculty Building

Clinical Research Office

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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