

# Efficacy of subcutaneous interleukin-2 (IL-2) in the treatment of advanced HIV-1 infections in persons with CD4+ T lymphocytes <100/mm<sup>3</sup> and undetectable plasma viral load

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 10/09/2012	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

Dr A Bonington

### Contact details

Infectious Diseases  
Delaunays Arch  
North Manchester General Hospital  
Delaunays Rd, Crumpsall  
Manchester  
United Kingdom  
M8 5RB  
+44 0161-720-2729  
[alec.bonington@pat.nhs.uk](mailto:alec.bonington@pat.nhs.uk)

## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N0155102865

## **Study information**

**Scientific Title**

**Study objectives**

Will IL-2 increase CD4+ counts in HIV -1 infected patients with advanced disease but undetectable viral load on HAART?

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Added June 2008: North Manchester Research Ethics Committee, ref NOR/00/103, 11/04/2001.

**Study design**

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 details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Infections and Infestations: Human immunodeficiency virus (HIV)

**Interventions**

30 patients randomised to highly active antiretroviral therapy (HAART) + IL-2 or HAART alone after 16 weeks, all patients -> IL-2

10/09/2012: Please note that this trial was stopped in 2009 due to a lack of participants

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

interleukin-2 (IL-2)

**Primary outcome measure**

Rise in CD4 count by >50% above baseline.

**Secondary outcome measures**

Proportion of subjects with final HIV RNA <400 copies/ml.

**Overall study start date**

17/04/2001

**Completion date**

31/05/2009

**Reason abandoned (if study stopped)**

Participant recruitment issue

## **Eligibility**

**Key inclusion criteria**

Added June 2008:

1. Age equal to or greater than 18 yrs old
2. HIV seropositive
3. On HAART (3 or more antiretroviral drugs)
4. HIV viral load < 400 copies/ml for  $\geq 3$  months
5. CD4 count  $\leq 100$  cells/mm<sup>3</sup> despite points 3. & 4. above

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Not Specified

**Target number of participants**

30

**Key exclusion criteria**

Added June 2008:

1. Active infection under investigation or treatment

2. Predicted poor compliance or poor attender
3. Pregnancy or breast-feeding
4. On-going treatment with interferon
5. Previous adverse reaction to IL-2
6. Clinically significant cardiac, pulmonary thyroid or neurologic impairment
7. Malignancy requiring systemic chemotherapy
8. Hb<9.5 g/dl, platelet count < 75,000/mm<sup>3</sup>, absolute neutrophil count < 1000 cells/mm<sup>3</sup>, serum creatinine> 2 times upper limit of normal (ULN), ALT >5 times ULN, bilirubin >2 times ULN (protease-induced hyperbilirubinaemia > 5 times ULN), amylase >2 times ULN

**Date of first enrolment**

17/04/2001

**Date of final enrolment**

31/05/2009

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre****Infectious Diseases**

Manchester

United Kingdom

M8 5RB

## Sponsor information

**Organisation**

Department of Health (UK)

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

North Manchester Healthcare NHS Trust (UK)

## **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