

Efficacy of subcutaneous interleukin-2 (IL-2) in the treatment of advanced HIV-1 infections in persons with CD4+ T lymphocytes <100/mm³ and undetectable plasma viral load

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Rise in CD4 count by >50% above baseline.

Key secondary outcome(s)

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

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 ≥ 3 months
5. CD4 count ≤ 100 cells/mm³ despite points 3. & 4. above

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

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/mm³, absolute neutrophil count < 1000 cells/mm³, 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

United Kingdom

England

Study participating centre

Infectious Diseases

Manchester

United Kingdom

M8 5RB

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

North Manchester Healthcare NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration