ISRCTN34382898 https://doi.org/10.1186/ISRCTN34382898

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

Submission date
12/09/2003

Recruitment status
Stopped

Registration date
12/09/2003

Overall study status
Stopped

Last Edited
10/09/2012

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] 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

Contact name
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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.

Study design
Randomised controlled trial

Primary study design
Interventional

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 than18 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