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# Randomised placebo-controlled trial of adefovir dipivoxil in patients with Human immunodeficiency virus (HIV) infection

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| **Submission date**<br>03/10/2000 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>03/10/2000 | **Overall study status**<br>Completed | |
| **Last Edited**<br>14/07/2014 | **Condition category**<br>Infections and Infestations | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
G9719209

# Study information

### Scientific Title

### Acronym
ADHOC

### Study objectives
To assess the efficacy and safety of adefovir dipivoxil in patients with advanced HIV-1 infection.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
HIV, Acquired Immunodeficiency Syndrome (AIDS)

### Interventions
Adefovir dipivoxil/placebo

### Intervention Type
Drug

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Adefovir dipivoxil

### Primary outcome measure

Primary endpoints are: changes in plasma HIV RNA by 8 and 24 weeks.

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/07/1997

### Completion date
30/06/2000

## Eligibility

### Key inclusion criteria
1. HIV infection, aged 13 or more
2. Any stage of HIV disease except prior or currently active Cytomegalovirus (CMV) disease
3. Last CD4 count less than 100: 100-200 if ever less than 50 in the past
4. Can at least care for himself or herself
5. No changes to other anti-HIV drugs for the past 8 weeks
6. Are considered likely to survive for more than 3 months
7. Able to comply and give informed consent

### Participant type(s)
Patient

### Age group
Other

### Sex
Both

### Target number of participants
307

### Key exclusion criteria
1. Prior or current treatment with ganciclovir, forcamet, cidofovir and valacyclovir
2. Other anti-CMV drugs; interferons, immune modulators or CMV globulin within 30 days
3. Needing parenteral therapy for a serious infection
4. Receiving, or likely to receive, a course of systemic chemotherapy for cancer
5. Significant malabsorption, nausea or vomiting
6. Ocular opacities or retinopathy preventing the diagnosis of CMV retinitis
7. Pregnant, breastfeeding or pregnancy not excluded, or not taking adequate contraception if of childbearing potential

### Date of first enrolment
01/07/1997

### Date of final enrolment
30/06/2000

# Locations

### Countries of recruitment
Australia

England

United Kingdom

### Study participating centre
**MRC Clinical Trials Unit**
London
United Kingdom
NW1 2DA

# Sponsor information

### Organisation
Medical Research Council (MRC) (UK)

### Sponsor details
20 Park Crescent
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W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

### Sponsor type
Research council

### Website
http://www.mrc.ac.uk

# Funder(s)

### Funder type
Research council

### Funder Name
Medical Research Council (MRC) (UK)

### Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### 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 | 01/10/2002 | | Yes | No |