

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

Submission date 03/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 03/10/2000	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/07/2014	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
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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**

United Kingdom

England

Australia

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

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