ISRCTN57857428 https://doi.org/10.1186/ISRCTN57857428

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
Registration date 03/10/2000	**Overall study status** Completed
Last Edited 14/07/2014	**Condition category** Infections and Infestations

✓ Retrospectively registered
? Protocol not yet added
? SAP not yet added
✓ Results added
? Raw data not yet added
✓ Study completed

Plain English Summary
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

Protocol/serial number
G9719209

Study information

Scientific Title

Acronym
ADHOC

Study hypothesis
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

Condition
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

Overall study end date
30/06/2000

Eligibility

Participant 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

Participant 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

Recruitment start date
01/07/1997

Recruitment end date
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)
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