

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

☐ Prospectively registered

☐ Protocol

Registration date
03/10/2000

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
14/07/2014

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Malcolm Hooker

Contact details

MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

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