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Trial of aciclovir in the prophylaxis of herpes infections in critical care

Submission date	Recruitment status	[X] Prospectively registered
13/02/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/03/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/05/2022	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

Clinical Trials Information System (CTIS)
2006-000612-24

Protocol serial number
WN06AN002

Study information

Scientific Title
Trial of aciclovir in the prophylaxis of herpes infections in critical care

Acronym
TRAPHICC

Study objectives
The overall aim of this proof of concept study is to serve as a pilot study for a multicentre study powered to detect improvement in Intensive Care Unit (ICU) mortality by giving aciclovir prophylaxis to prevent Herpes Simplex Virus (HSV) infection in the lungs.

As of 01/06/2009 this record has been updated to include an extension to the anticipated end date; the initial end date at the time of registration was 31/05/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Multi-Centre Research Ethics Committee for Scotland (Committee A) approved on the 28/03 /2008 (ref: 06/MRE00/14; Protocol Number: 3; EudraCT Number: 2006-000612-24).

Study design
Double-blind, randomised, parallel group placebo-controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Herpes simplex virus infection of the lower respiratory tract in critically ill patients

Interventions
Administration of 15 mg/kg per day aciclovir or placebo by infusion three times daily over 1 hour

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Aciclovir

Primary outcome(s)
The primary endpoint is the mean change in Karnofsky index from baseline to day 28 +/- 2 days and 90 +/- 2 days after entry to the study

Key secondary outcome(s))
1. Proportion of patients with HSV detected during ICU stay in lower respiratory secretions; proportion of patients with HSV detected during ICU stay in blood samples
2. In patients in whom HSV is detected during ICU stay, proportions of infections due to primary

infection and reactivation of latent infection
3. At each sampling time point, the correlation between HSV lymphocyte response and viral titres
4. Mean plasma soluble cytokine levels in patients with and without HSV infection; mean respiratory secretion soluble cytokine levels in patients with and without HSV infection
5. Proportions of patients with HSV reactivation according to type of cytokine response
6. Mean complement activation before HSV is detected, after HSV detection and in patients where HSV is not detected during ICU stay
7. Proportion of patients in whom each of Cytomegalovirus (CMV), Epstein-Barr Virus (EBV), Human Herpes Virus Six (HHV6) and Human Herpes Virus Seven (HHV7) infections are detected during ICU stay
8. Median number of days on ventilation, median ICU stay, frequency of prescription of each of anti-retroviral agents, corticosteroids, immunosuppressive agents
9. Proportion of patients surviving at 90 days following ICU admission
10. Number of days of survival following ICU admission
11. The survival time for patients surviving beyond 90 days will be censored at 90 days
12. Proportion of HSV infections which are HSV1, proportion of HSV infections which are HSV2
13. Mean vital signs, white cell count and creatinine clearance during ICU stay
14. Reporting of adverse events occurring during randomised treatment or during the 7 days following the end of randomised treatment

Completion date
30/09/2009

Eligibility

Key inclusion criteria
1. All patients 18 years or over entering ICU
2. Patient expected to stay in the ICU longer than 36 hours and intubated with an endotracheal or tracheostomy tube within 24 hours of admission to ICU
3. Patient not requiring treatment with aciclovir, valaciclovir, ganciclovir, foscarnet, probenicid or other drug known to have anti-herpes simplex activity
4. Patient must have no known allergy to aciclovir
5. Females of childbearing age must have negative pregnancy test on admission
6. Written informed consent from the patient or assent obtained from relatives

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Duration of admission confidently expected to be less than 36 hours
2. Patients with endotracheal or tracheostomy tube placed more than 24 hours before admission to ICU
3. Patient has clinical features of HSV disease
4. Patient previously randomised to this study
5. Patients deemed to be suitable for entry to another trial
6. Previous hypersensitivity to aciclovir or valaciclovir
7. Patient requiring agent with anti-herpes virus activity
8. Patient previously enrolled in another trial of an investigational drug within the past 30 days
9. Patient is pregnant or lactating

Date of first enrolment
01/06/2006

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Intensive Therapy Unit
Glasgow
United Kingdom
G11 5JR

Sponsor information

Organisation
Greater Glasgow Health Board (North Glasgow University Hospitals Division) (UK)

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office of the Scottish Executive Health Department (UK) (ref: CZB/4/375)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		04/02/2021	19/05/2022	No	No