

A pharmacokinetic and pharmacodynamic study of valganciclovir in solid organ transplant patients

Submission date 11/12/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/02/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/07/2021	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

A pharmacokinetic and pharmacodynamic study of valganciclovir in solid organ transplant patients

Study objectives

Valganciclovir is a prodrug of ganciclovir with improved oral bioavailability, potentially useful for the treatment of Cytomegalovirus (CMV) infection in organ transplant recipients and for the prophylaxis of CMV infection in liver and lung transplant patients, two indications currently not validated. Our hypothesis is that valganciclovir produces drug levels and virological responses similar to those obtained with intravenous ganciclovir. This would provide indirect evidence for the use of oral valganciclovir instead of intravenous ganciclovir within the settings mentioned above.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received by the local ethics committee (Commission d'éthique de la recherche clinique, Faculté de Médecine et Biologie, Université de Lausanne) on the 20th September 2005 (ref: 94 /05).

Study design

Prospective observational trial with historical controls

Primary study design

Observational

Secondary study design

Case-control study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Cytomegalovirus (CMV) infection

Interventions

Patients will receive valganciclovir (900 mg once daily [QD], adjusted to their renal function according to the information provided by the manufacturer), over three months, for primary prophylaxis. During such period, blood samples will be collected monthly to determine ganciclovir plasma levels (immediately before and three hours after oral administration) and

CMV blood viral loads will be measured by real time quantitative Polymerase Chain Reaction (PCR). Upon the initial prophylaxis termination, and over the following three months, universal blood monitoring for CMV infection will continue on a fortnightly basis.

In case of detection of high viremia level (more than 10,000 - 100,000 copies of CMV Deoxyribonucleic Acid [DNA]/million leukocytes) and/or symptomatic CMV disease, patients will receive therapeutic dosages of valganciclovir (900 mg twice daily [bid], adjusted to renal function) until they achieve a clinical response or their viral load drops. Throughout such treatment phase, ganciclovir plasma level and CMV viral load assays will be performed weekly. Treated subjects will then receive secondary prophylaxis (half the therapeutic dose of valganciclovir, 900 mg QD, adjusted to renal function) for one month, with fortnightly ganciclovir plasma levels and CMV viral load assays. In selected patients, treating physicians may opt at their discretion for intravenous ganciclovir rather than oral valganciclovir, based on their clinical judgement. Any such patients will have plasma levels and CMV viral load tested weekly.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Valganciclovir

Primary outcome measure

1. To determine whether the average ganciclovir blood levels following the oral administration of valganciclovir are comparable to the known therapeutic range associated with the use of intravenous ganciclovir
2. To assess the variability of ganciclovir blood levels attained with oral valganciclovir, to evaluate its potential repercussions on therapeutic response, and to identify influential factors which modulate valganciclovir absorption and disposition

Secondary outcome measures

1. To evaluate the relationship between ganciclovir blood levels and anti-CMV efficacy using a pharmacokinetic-pharmacodynamic model incorporating the relevant pharmacokinetic, virological and clinical response parameters
2. To determine the impact of specific clinical conditions (malabsorption, cystic fibrosis, kidney failure), concomitant medications (drugs inhibiting organic anion transport) and possibly genetic traits (drug transporters polymorphisms) on ganciclovir and valganciclovir pharmacokinetics and dose requirements
3. To further assess the safety and tolerability of oral valganciclovir

Overall study start date

15/11/2005

Completion date

31/12/2007

Eligibility

Key inclusion criteria

1. Solid organ transplant recipient
2. More than or equal to 18 years old
3. At risk for CMV disease (D+/R-, D+/R+ or D-/R+)
4. Written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

100

Key exclusion criteria

1. Failure to give written informed consent
2. Known intolerance to ganciclovir or valganciclovir

Date of first enrolment

15/11/2005

Date of final enrolment

31/12/2007

Locations**Countries of recruitment**

Switzerland

Study participating centre

Division de Pharmacologie et Toxicologie Cliniques

Lausanne

Switzerland

1011

Sponsor information**Organisation**

University Hospital Complex of Vaud (Centre Hospitalier Universitaire Vaudois [CHUV])
(Switzerland)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.chuv.ch/>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Hospital Complex of Vaud (Centre Hospitalier Universitaire Vaudois [CHUV])
(Switzerland)

Funder Name

Roche (Switzerland) - unrestricted grant

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?
Thesis results		26/05/2008	19/07/2021	No	No