Valchek

Valganciclovir Hydrochloride 450 mg Tablets

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BACKGROUND

- Cytomegalovirus (CMV) is the most common opportunistic pathogen in solid organ transplant recipients.
- The main challenge consists of indirect effects associated not only with CMV disease but also with asymptomatic CMV viremia.
- Prevention of cytomegalovirus (CMV) is essential in organ transplantation. The two main strategies are pre-emptive therapy, in which one screens for and treats asymptomatic CMV viremia, and universal antiviral prophylaxis.
- The pre-emptive valganciclovir therapy may lead to less severe interstitial fibrosis and tubular atrophy and to significantly better graft survival.[3]

CLINICAL EVIDENCE

Valganciclovir Prophylaxis versus Preemptive Therapy in Cytomegalovirus-Positive Renal Allograft Recipients : 1-Year Results of a Randomized Clinical Trial

Background - Cytomegalovirus (CMV) prevention can be achieved by prophylaxis or pre-emptive therapy. We performed a prospective randomized trial to determine whether renal transplant recipients with a positive CMV serostatus (R+) had a higher rate of CMV infection and disease after transplantation when treated preemptively for CMV infection, compared with primary valganciclovir prophylaxis.

Methods - Prophylaxis was 2×450 mg oral valganciclovir/day for 100 days; preemptive patients were monitored by CMV-polymerase chain reaction (PCR), and after a positive PCR test received 2×900 mg valganciclovir/day for at least 14 days followed by secondary prophylaxis. Valganciclovir dosage was adjusted according to renal function. Patients are followed up for 5 years and initial 12-month data are presented. Two hundred and ninety-six recipients were analyzed (168 donor/recipient seropositive [D+/R+], 128 donor seronegative / recipient seropositive [D−/R+]; 146 receiving prophylaxis and 150 preemptive therapy).

Results - Overall, CMV infection was significantly higher in recipients under preemptive therapy, with the highest incidence in D+/R+ preemptive patients (53.8% vs. 15.6%, $P<0.0001$). D+/R+ recipients with preemptive therapy also had the highest rate of CMV disease. Renal function assessed by creatinine clearance was similar for both groups. Graft loss occurred in 7 vs. 4 patients on preemptive versus prophylactic therapy ($P>0.05$). Tolerability was similar for both treatment groups.

Conclusions - Oral valganciclovir prophylaxis significantly reduces CMV infection and disease, particularly for D+/R+ patients. Hence, our study supports routine prophylaxis for all D+/R+ recipients.

LONG-TERM OUTCOMES OF PRE-EMPTIVE VALGANCICLOVIR COMPARED WITH VALACYCLOVIR PROPHYLAXIS FOR PREVENTION OF CYTOMEGALOVIRUS IN RENAL TRANSPLANTATION

Background - Prevention of cytomegalovirus (CMV) is essential in organ transplantation. The two main strategies are Pre-emptive therapy, in which one screens for and treats asymptomatic CMV viremia, and universal antiviral prophylaxis.

Method - We compared these strategies and examined long-term outcomes in a randomized, open-label, single-center trial. We randomly assigned 70 renal transplant recipients (CMV-seropositive recipient or donor) to 3-month prophylaxis with valacyclovir (n=34) or pre-emptive valganciclovir for significant CMV viremia detected at predefined assessments through month 12 (n=36).

Results - Among the 55 patients who had a protocol biopsy specimen available at 3 years to allow assessment of the primary outcome, 9 (38%) of 24 patients in the prophylaxis group and 6 (19%) of 31 patients in the pre-emptive therapy group had moderate to severe interstitial fibrosis and tubular atrophy.
The prophylaxis group had significantly higher intra renal mRNA expression of genes involved in fibrogenesis. The occurrence of CMV disease was similar in both groups, but pre-emptive therapy improved 4-year graft survival as a result of worse outcomes in patients with late-onset CMV viremia.

Conclusions - In conclusion, compared with valacyclovir prophylaxis, pre-emptive valganciclovir therapy may lead to less severe interstitial fibrosis and tubular atrophy and to significantly better graft survival.

WHY VALCHEK ?

- Valganciclovir therapy was shown to have similar effectiveness in the prevention of symptomatic CMV disease after renal transplantation.[1]
- Valganciclovir, the oral valine pro drug of ganciclovir, is effective for the primary prevention of CMV disease after solid organ transplantation.[2]
- Oral valganciclovir is not inferior to intravenous ganciclovir for the treatment of CMV disease in renal transplant recipients.[2]

REFERENCES

1. American Journal of Transplantation 2010; 10: 1228–1237
2. Nature clinical practice; Nephrology: 4(1) ;2008
3. J Am Soc Nephrol 23: 1588–1597, 2012
4. Clinical and Translational Research: 15:61-68;2012

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DESCRIPTION

- VALCHEK™ is an antiviral drug used to treat CMV (cytomegalovirus) infections.
- VALCHEK™ contains valganciclovir HCl, a hydrochloride salt of the L-valyl ester of ganciclovir that exists as a mixture of two diastereomers.
- Ganciclovir is a synthetic guanine derivative active against CMV. Valganciclovir, it is actually a prodrug for ganciclovir.
- CMV is one of the most serious infections affecting transplant patients.
- Valchek works by slowing the ability of CMV to reproduce itself within the body, helping to prevent CMV disease in transplant patients.

INDICATION

- VALCHEK™ oral tablets are indicated for the prevention of CMV (cytomegalovirus) disease in kidney transplant patients.

MECHANISM OF ACTION

- Valganciclovir is an L-valyl ester (prodrug) of ganciclovir that exists as a mixture of two diastereomers.
- In CMV-infected cells ganciclovir is initially phosphorylated to ganciclovir monophosphate by the viral protein kinase, pUL97.
- Further phosphorylation occurs by cellular kinases to produce ganciclovir triphosphate, which is then slowly metabolized intracellularly (half-life 18 hours).
- As the phosphorylation is largely dependent on the viral kinase, phosphorylation of ganciclovir occurs preferentially in virus-infected cells.
- The virustatic activity of ganciclovir is due to inhibition of viral DNA synthesis by ganciclovir triphosphate.

DOSAGE

For adult patients who have received a kidney transplant, the recommended dose is 900 mg (two 450 mg tablets) once a day starting within 10 days of transplantation until 200 days post-transplantation.

ADMINISTRATION

VALCHEK™ is available as a 450 mg tablet for oral administration.

PRESENTATION

Available as a strip of two tablet of Alu-PVDC blister packing.

La Renon Healthcare Pvt. Ltd.

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