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Oral vs Intravenous Ganciclovir (GCV) as Maintenance Treatment of Newly Diagnosed Cytomegalovirus Retinitis (CMVR) in AIDS. JP LALEZARI, Mt. Zion Medical Center of University of California, San Francisco, for the SYNTEX COOPERATIVE ORAL GCV STUDY GROUP.

**STUDY DESIGN:** This study was designed to determine if progression on oral GCV was no worse by 25 days compared to i.v. GCV as maintenance treatment for newly diagnosed CMVR. Individuals with a new diagnosis of CMVR received 3 weeks of i.v. GCV and, if the CMVR was stable, were randomized to i.v. GCV maintenance of 5 mg/kg QD or oral GCV at 500 mg 6X/day (3000 mg/day) for 20 weeks. Visual acuity measurement, dilated indirect ophthalmoscopy, and fundus photographs were done every 2 weeks, with photographs evaluated at a masked reading center. The two groups were balanced at randomization except that those assigned to oral GCV (n=60) had a diagnosis of AIDS 5 months longer, while the i.v. GCV group (n=57) had lower Karnofsky scores.

| **RESULTS:** | I.V.GCV | Oral GCV | p-value |
|---|---|---|---|
| Days to Progression (mean/median) | | | |
| By Fundoscopy | 96/111 | 68/48 | 0.028* |
| By Photographs | 62/49 | 57/29 | 0.607* |
| Worsened Visual Acuity (either eye) | 15/57 | 12/60 | 0.512 |
| CMV Culture pos on Rx | 3/47 | 4/42 | |

*Logrank test comparing means of Kaplan-Meier survival curves.

**CONCLUSION:** Oral GCV was well tolerated, and there were no differences in gastrointestinal adverse events between treatments. Neutropenia (ANC <500), fever, and sepsis occurred more often in the i.v. GCV group. Oral GCV demonstrated an anti-CMV effect comparable to i.v. GCV. There was no statistically significant difference in visual acuity outcome. Using the equivalence definition as no more than a 25 day difference in time to progression, oral GCV was worse than i.v. GCV by funduscopic evaluation, but the two treatments were equivalent by masked photography.