

**TITLE: Valganciclovir Four Weeks Prior to cART
Initiation Compared to Standard Therapy for
Disseminated Kaposi Sarcoma**

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Statistical analysis

Sample size was calculated for a study power of 80% and an alpha of 0.05, with an estimated event rate (IRIS) in the control group of 40%, and in the treated group of 5%. The number estimated in each group was 19, for a total sample of 38 patients.

Descriptive statistics were performed, including the number of deaths, and episodes of S-IRIS-KS, in the CG and EG groups. Comparisons between EG and CG were performed, as intention-to-treat (ITT), and as per-protocol analysis, for the primary outcome of mortality attributed to S-IRIS-KS using Proportional-Hazard Cox models.

In addition, we compared the impact of treatment on repeated episodes of S-IRIS-KS by multivariate Poisson model and by the number of participants with at least one S-IRIS-KS event, as repeated events can occur in the same patient, and the total number of events may be due to a few very susceptible individuals.

Statistical models were adjusted by baseline CD4+, CD4+/CD8+ cell ratio, HHV-8 and HIV VL, plasmatic IL-6, CRP and by the presence of concomitant coinfections. Analyses were performed using Stata Statistical program.