

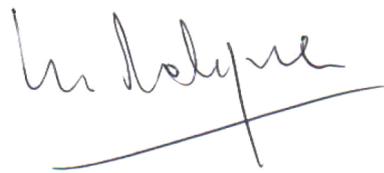
Statistical analysis

Except for safety analyses, in which the safety population was used, statistical analyses were performed in the population per protocol (PPP) function of statistical software R version 3.10.0^[23]. For the hypothesis contrasts, an alpha risk of 0.05 was assumed. The included p-values were calculated based on bilateral contrast without adjustment for the performance of multiple contrasts.

For comparison of the percentage of patients maintaining a sustained virologic response at 48 weeks of study and to evaluate differences in AE incidence in the 2 arms, Fisher's exact test was used.

To evaluate differences in the evolution of hepatic and renal function, differences between baseline values and those obtained at weeks 12, 24, 36 and 48 were compared by hypothesis contrast using the Friedman test.

In the cost analysis, differences between costs were compared using the Mann-Whitney U test.

A handwritten signature in black ink, appearing to read 'L. Dolyn', with a long horizontal stroke underneath.