For all lipid-related parameters, only small increases were seen from baseline to Week 48 in triglycerides were smaller for once-daily DRV/r compared with twice-daily DRV/r—the median triglyceride levels in the once-daily DRV/r arm remained below the NCEP cut-off throughout the treatment period. For total cholesterol, the median percentage increases from baseline to Week 48 were smaller for once-daily versus twice-daily DRV/r—median cholesterol levels remained below the NCEP cut-off for both treatment groups.

Small changes in total cholesterol were observed in median levels of LDL calculated and HDL for both treatment arms.

Table 1. Demographics, disease characteristics and lipid levels at baseline.

Table 2. Lipid-related AEs overall and at least possibly related to DRV/r during the treatment period (regardless of severity).

Mean exposure 43.1 weeks

Table 3. Treatment-emergent, lipid-related laboratory abnormalities.

Lipid-related laboratory abnormalities

The majority of lipid-related laboratory abnormalities were grade 1 or 2 in severity.

The most frequent lipid-related laboratory abnormality was total cholesterol—grade 2 or 3 increases in total cholesterol occurred in 10.1% of patients in the once-daily DRV/r arm compared with 20.6% of patients in the twice-daily DRV/r arm (Table 3).

Table 4. NCEP treatment-emergent lipid-related laboratory abnormalities of interest to Week 48 in patients not receiving lipid-lowering agents.

Conclusions

- Lipid-related AEs were reported less frequently in the once-daily DRV/r group than in the twice-daily DRV/r group.

- The incidence of grade 2–4 triglyceride elevations with once-daily DRV/r was approximately half that of twice-daily DRV/r.

- At Week 48, the incidence of NCEP treatment-emergent triglyceride and total cholesterol laboratory abnormalities was significantly lower with once-daily DRV/r compared with twice-daily DRV/r in patients not receiving lipid-lowering agents.

- Overall, small increases in median lipid levels for all lipid parameters were seen in both the once- and twice-daily DRV/r arms— from baseline to Week 48, the median increases in triglycerides were smaller for once-daily DRV/r compared with twice-daily DRV/r.

- Safety and tolerability data from ODIN confirm that once-daily DRV/r was well tolerated with a favourable lipid profile in treatment-experienced, HIV-1-infected patients over 48 weeks.

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References


