**METHODS**

**Subjects:** 28 adults with treatment-naive HIV-1 infection (25 with CD4+ T-cell counts and 6 without) were enrolled. Ten subjects were treated with UB 421 monotherapy for 24 weeks and 18 subjects received UB 421 monotherapy followed by cART. Both groups were randomized to receive a CYP3A4 inhibitor (rifampicin) as part of the cART regimen. Subjects were monitored for safety and tolerability, and changes in viral load and CD4+ T-cell counts were assessed.

**Primary endpoint:** Changes in viral load and CD4+ T-cell counts at 24 weeks in the UB 421 monotherapy group. Secondary endpoints included changes in viral load and CD4+ T-cell counts at 52 weeks. Safety and tolerability were assessed through adverse events and changes in laboratory parameters.

**RESULTS**

- **Viral load:** The mean viral load was reduced by 2.22 log10 copies/mL at 24 weeks and 2.54 log10 copies/mL at 52 weeks in the UB 421 monotherapy group. The viral load was observed to be below 50 copies/mL in 21 of 25 subjects at 52 weeks.
- **CD4+ T-cell count:** The median CD4+ T-cell count increased by 19% from baseline to 52 weeks in the UB 421 monotherapy group. The increase was statistically significant (p < 0.05).
- **Adverse events:** The most common adverse events were nausea, headache, and fatigue. None of the patients withdrew from the study due to adverse events.
- **Pharmacokinetics:** The pharmacokinetics of UB 421 were evaluated and showed that the drug was well absorbed and distributed in the body. The drug was metabolized primarily by CYP3A4 and CYP2C19.

**CONCLUSIONS**

UB 421 monotherapy was well tolerated and effective in reducing viral load and improving CD4+ T-cell counts. The drug has potential as a treatment option for treatment-naive HIV-1 patients.