Background

Introduction: HIV post-exposure prophylaxis (PEP) completion rates are of major concern, as rates of individuals completing the 28-days course regimen range from 56 to 78%.

Recently, the elvitegravir/cobicistat/tenofovir/alcplafenamide coformulation (E/C/TAF) was approved for HIV infection treatment. This single tablet regimen (STR) contains a new prodrug, tenofovir alafenamide, which could improve the safety profile of tenofovir.[10]

Objectives: To describe PEP completion and safety of an E/C/F/TAF regimen.

Methods

Study settings and design: Prospective, open-label, single-arm trial in 15 French centers (NCT02998320).

Individuals aged ≥18 years with potential exposure to HIV (occupational or not) in the previous 48 hours who met criteria for PEP initiation received once-daily E/C/TAF for 28 days.

Assessments: The primary endpoint was PEP completion at day 28, excluding withdrawal after patient was tested negative to HIV.

Secondary endpoints were:
1. Adherence: through self-report (day 14 and 28) and elvitegravir blood plasma level (day 14)
2. Quality of life: through SF-12 questionnaire (day 14 and 28) and biological parameters (creatinine, GFR, AST, ALT, phosphate) (day 14, day 28 and day 112)
3. Safety: through questionnaire (day 112) and biological parameters (blood plasma level [day 14].

Results

Participants were primarily male (75%, 77%) with a median age of 31 years (range, 18-69).

Exposures to HIV were: - occupational: 48 sexual, of which 64% were MSM and 47% were heterosexual, of which 64% were MSM and 47% were heterosexual.

Six source patients were known to be HIV-infected (no HIV-RNA available).

Adherence

Self-reported adherence was 100%, between 90 and 99%, and <99% for 76%, 22% and 2% of individuals at day 14, and for 75%, 17% and 8% of individuals at day 28, respectively (p=0.05) (see Figure A)

Health-related quality of life

Mean quality of life SF-12 measures of physical and mental health were of 50 (range, 27-64) and 47 (range, 17-65) at baseline, 52 (range, 25-64) and 48 (range, 25-67) on day 14, and 51 (range, 26-64) and 49 (range, 22-61) on day 28, respectively (p=0.05) (see Figure B)

Conclusion

The PEP completion rate was of 81%, thus in the range of other recently approved STR when used in a PEP setting. PEPE non-completion was not directly attributed to E/C/TAF, but mostly to losses of follow-up, which frequently hampers PEP care.

We also report a 100% efficacy rate, as no participant was subsequently tested HIV positive on study. High adherence (>90% of pills intake) to the E/C/TAF regimen was documented by both self-reports in 98% and 92% at day 14 and 28 respectively, as well as by pharmacological assessments (appropriate in 88% of cases). These results were similar than those obtained with other PEP STR.

Quality of life measures were not modified on E/C/TAF and were similar than those of the general population, suggesting that E/C/TAF is suitable for further PEP usage.

Overall, PEP E/C/TAF showed an acceptable safety profile and good completion rates. Self-reported and drug levels indicated good adherence, confirming that E/C/TAF could be a regimen of choice for PEP.