pVL at week 48 failure:73.8 copies/mL.Mean CD4+ change from baseline:TT:+238.1 cells/uL, DT:+275.3 cells/mm3 (p:0.4).Fifty-nine grade 2-3 related adverse events (AEs) were reported among 53 patients(TT:33 / DT:20, p:0,04). Most frequent were:rash (TT:5%; DT: 6%; p:0.70), diarrhea (TT: 5%; DT: 1%; p:0.06**),abdominal pain (TT: 5%; DT: 1%; p:0.03). AEs leading to discontinuation were rare (TT:2, DT:2).Two possible treatment-related SAEs were reported (both lipase increase G4)in TT arm.Laboratory changes from baseline to week 48 were similar except to lipid profile with higher change in DT arm:total cholesterol (TT:8%;DT:20%;p<0.01) ,LDL-cholesterol (TT:8%;DT:19%;p:0.01),Triglycerides(TT:38%;DT:56%;p=0.05).
Conclusions: A generic FDC of DRV/r plus 3TC showed non-inferiority to standard TT with DRV/r plus TDF/3TC at 48 weeks in both ITTe and per-protocol populations.The DT strategy was safe and well tolerated and could be considered as an alternative option for treatment naïve population.

OAB0304

Dolutegravir versus efavirenz-400 as first-line ART in Cameroon: week 192 data of NAMSAL trial

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Background: The NAMSAL main objective was the comparison of two first-line antiretroviral treatments (ARTs) in real-life conditions in low- and middle-income countries (LMIC): dolutegravir 50 mg (DTG) and low-dose of efavirenz (ie 400 mg; EFV400) daily both combined with tenofovir-disoproxil-fumarate [TDF]/lamivudine [3TC]. The 48-week outcomes provided decision-making elements to World Health Organization (WHO) to recommend DTG as first-line ART in 2019. Outcomes were confirmed at 96 weeks. We assessed long-term efficacy and safety of these two regimens.
Methods: NAMSAL was an open-label, multicenter, randomized, phase 3 non inferiority trial conducted in Cameroon over 96-week, extended as post-trial follow-up as a prospective cohort until 192-week. HIV-1 infected ARV-naive adults with HIV-RNA viral load (VL)>1000 copies/mL were randomized and maintained in the base arm (1-DTG:1-EFV). The primary end point was the proportion of participants with a VL of less than 50 copies/mL at week 48; secondary outcomes were assessed with superiority-test.
Results: At week 192, proportions of participants with a VL of less than 50 copies/mL in intention-to-treat (ITT) were 69% (DTG: 214/310) and 62% (EFV400: 187/303) respectively (difference, 7.3%; CI-95%, [−0.20;14.83], p-value=0.057; Figure1). *Per-protocol* results were 75% (DTG: 172/230) and 66% (EFV400: 178/271) respectively (difference, 9.1%; CI-95%, [1.13;17.07], p-value=0.027). During the four-year of follow-up, five (DTG: 2; EFV400: 3) new virological failures (WHO-definition) without related resistance mutations and 24 new severe adverse-events (SAE) were observed (DTG: 13, EFV400: 11). Over four years, weight gain was more important on DTG group compared to EFV400 group: Median weight-gain (Women (W): DTG +8.0 Kg, EFV400 +5.0 Kg, p-value=0.010; Men (M): DTG +6.0 Kg, EFV400 +4.0 kg; p-value=0.024); Obesity incidence (W: DTG 17%, EFV400 11%, p-value=0.140; M: DTG 26%, EFV400 4%; p<0.001); Proportion of patients who had a weight-gain of at least 15% compared to their initial weight (W: DTG 43%, EFV400 31%, p-value=0.030; M: DTG 23%, EFV400 25%; p- value= 0.848; Figure 2).
Conclusions: DTG-based and low dose EFV-based regimens has durable efficacy and safety for use in treatment-naïve patients with HIV-1. There was significantly more weight gain with the DTG-containing regimen.

OAB0305

Survival in advanced AIDS patients treated with efavirenz or dolutegravir in Brazil: a multicenter, observational study

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Background: Most of studies on integrase inhibitors efficacy were conducted on healthy patients. There is scarce information on DTG use in late-presenters HIV patients. We compared the effect of ART regimens based on Efavirenz (EFV) or Dolutegravir (DTG) on survival of patients with advanced AIDS.
Methods: We enrolled symptomatic AIDS patients starting therapy with a CD4 count<50 cells/ml in 5 Brazilian cities. We compared patients starting DTG-based ART (2018 to 2020) or EFV-based regimens (2013 to 2016), as controls regarding early mortality, rates of viral suppression at 24 and 48 weeks, changes in CD4 count, incidence of adverse events, and therapy discontinuation.
Results: We included 92 patients per arm mean age 39.4 (DTG) and 37.3 years (EFV), 68 % males, mean baseline CD4 count=23 cells/ml, mean HIV viral load= 5.5 copies/ml $\log_{10}$. Viral suppression rates (<50 copies/ml) were higher in DTG than in EFV group at 24 (67% vs 42%,) and at 48 weeks (65% vs 46%, p<0.01). At 48 weeks median CD4 count was similar for DTG and EFV groups (213 cells/ml vs. 222 cells/ml), but more patients in DTG group presented with CD4 >200 cells/ml (45% vs. 29%, p=0.03). Levels of total cholesterol(189 vs 168 mg/dL), triglycerides (188 vs 129 mg/dL) and VLDL cholesterol(35 vs 26 mg/dL) were higher in EFV than in DTG group (p<0.01 for comparisons). Creatinine levels were higher in DTG (0.97 mg/dL) than in EFV (0.86 mg/dL, p=0.02) group. Survival was higher in DTG group (figure 1), mostly driven by treatment changes (1% vs. 17%, p<0.0001) or loss to follow up (11% vs. 15%).
Conclusions: Advanced AIDS patients treated with DTG had a higher proportion of viral suppression/survival rate/ immune restoration, less lipids changes, and lower discontinuation rates after 48 weeks than patients treated com EFV. DTG is confirmed as a preferential option to treat advanced AIDS patients.

OAB0402

Efficacy and safety results in participants co-infected with HIV from TB-PRACTECAL Clinical Trial

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Background: Globally, TB/HIV coinfection accounts for 477461 notified cases and 456000 cases of rifampicin-resistant tuberculosis