

Abstract Supplement

HIV Glasgow

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Clinical Management Considerations **Opportunistic Infections**
Community-based treatment and prevention
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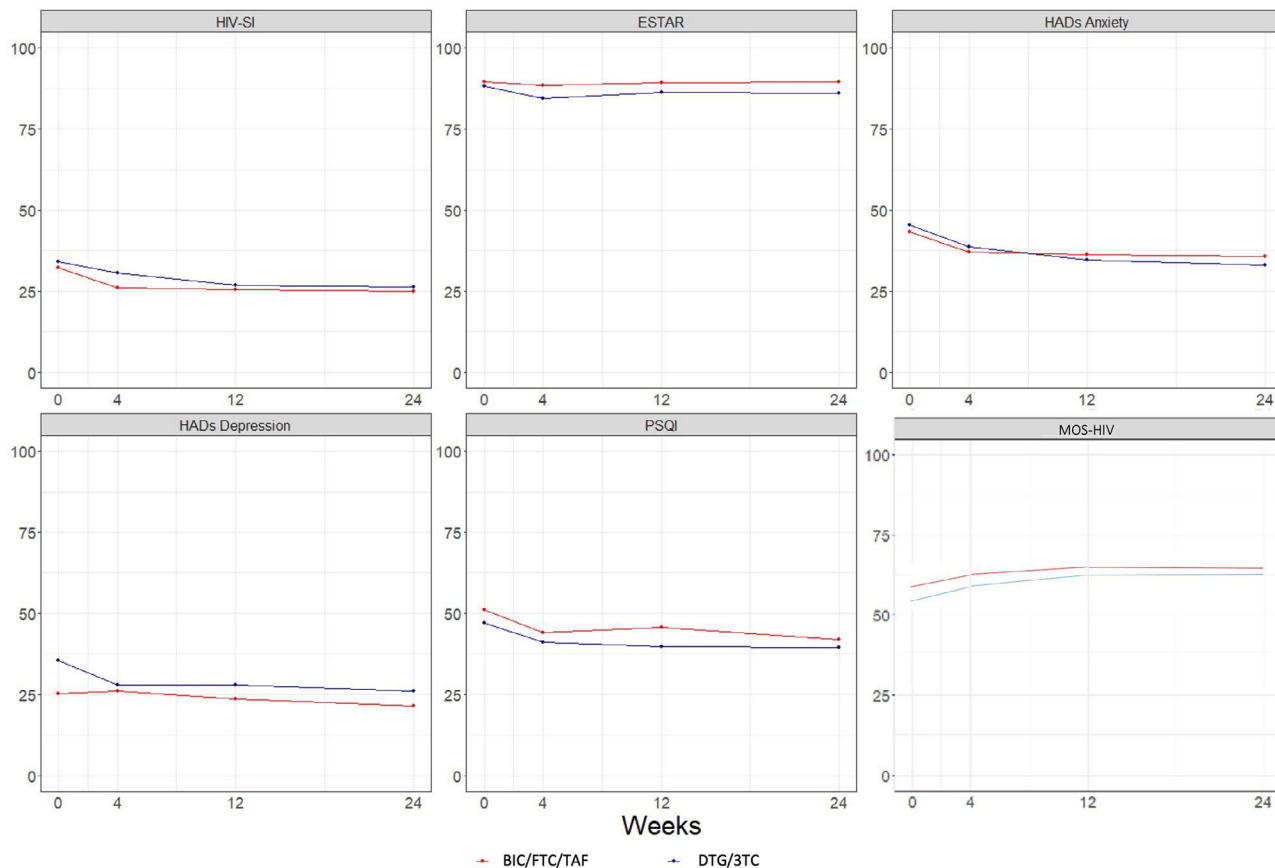
People living with HIV
 Clinical Pharmacology
 Cure/post treatment control
 Co-morbidities and Complications

O43

Randomized, multicentre, double-blind clinical trial designed to evaluate the safety and convenience of switching from dolutegravir/lamivudine to bictegravir/emtricitabine/tenofovir alafenamide in people with HIV, good virological control and neuropsychiatric

comorbidities: week 24 results from the GESIDA 11920 - MIND study

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O43: Figure 1. Evolution of normalized scores of self-reported questionnaires (HIV-SI, HADs, PSQI, ESTAR and MOS-HIV) up to week 24.

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Background: People with HIV (PWH) and pre-existing neuropsychiatric comorbidities (NPCs) have been systematically excluded from dolutegravir/lamivudine (DTG/3TC) clinical trials. Therefore, we do not know the neuropsychiatric safety profile of DTG/3TC in this population.

Materials and methods: The purpose of the MIND study, a double-blind, multicentre, randomized clinical trial, was to compare the neuropsychiatric safety of continuing on DTG/3TC versus switching to bicitegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in PWH with undetectable viral loads (HIV-RNA <50 copies/ml) and pre-existing NPCs.

We compared the proportion of discontinuations and neuropsychiatric adverse events (AEs) between groups, as well as self-reported changes in mood (Hospital Anxiety and Depression Scale; HADS), sleep (Pittsburgh Sleep Quality Index; PSQI), HIV-related symptoms (HIV Symptom Index; HIV-SI), quality of life (Medical Outcome Study-HIV Health Survey; MOS-HIV) and treatment satisfaction (Escala de Satisfacción con el Tratamiento Antirretroviral; ESTAR) after 24 (current analysis) and 48 weeks of follow-up. Generalized estimating equations and linear general models were used to evaluate the treatment effect on outcome variables.

Results: The study was fully recruited, with 39 participants continuing on DTG/3TC (arm 1) and 41 switching to BIC/FTC/TAF (arm 2). Baseline characteristics were similar between arms. At week 24, five participants discontinued treatment in DTG/3TC and BIC/FTC/TAF arms (average: 12.8% [4.8-30.1] vs. 12.2% [4.6-28.8]). Neuropsychiatric AEs leading to ART discontinuation (3 vs. 2) and grade 2-4 neuropsychiatric AEs (17.9% vs. 14.5%) were also similar between groups. The most common AEs with DTG/3TC were headache (15.4%), insomnia (7.7%) and anxiety/depression (both 5.1%), and with BIC/FTC/TAF, they were anxiety (14.6%), depression (7.3%) and insomnia (7.3%). Suicidality was documented in one participant on DTG/3TC (2.6%) and in two participants on BIC/FTC/TAF (4.9%) ($p = 0.59$). Changes in the HADS, PSQI, HIV-SI and MOS-HIV questionnaires were also similar between groups (Figure 1). Participants who switched to BIC/FTC/TAF experienced improvements in gastrointestinal tolerability (nausea: 3.9% vs. 23.2%, $p = 0.03$; abdominal discomfort: 16.8% vs. 40.2%, $p = 0.02$) and lipid profile (change in total cholesterol: -11.1 vs. 5.4 mg/dl; LDL: -13.1 vs. 4.2 mg/dl).

Conclusions: In PWH with pre-existing NPCs, switching from DTG/3TC to BIC/FTC/TAF did not show short-term neuropsychiatric safety benefits. However, improvements in gastrointestinal tolerability and lipid profile may justify the switch in PWH experiencing gastrointestinal intolerance and/or dyslipidaemia