

Poster Sessions – Abstract P274

## Atazanavir/ritonavir monotherapy as maintenance strategy in HIV-1 treated subjects with viral suppression: 96-week analysis results of the MODAT study

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**Introduction:** The 48-week interim analysis of the MODAT study showed that confirmed virologic failure (CVF) was more frequent in patients simplifying to ATV/r monotherapy compared to maintaining ATV/r-based triple therapy. The DSMB recommended stopping study enrollment but continuing follow-up of enrolled patients. We present the 96-week efficacy analysis.

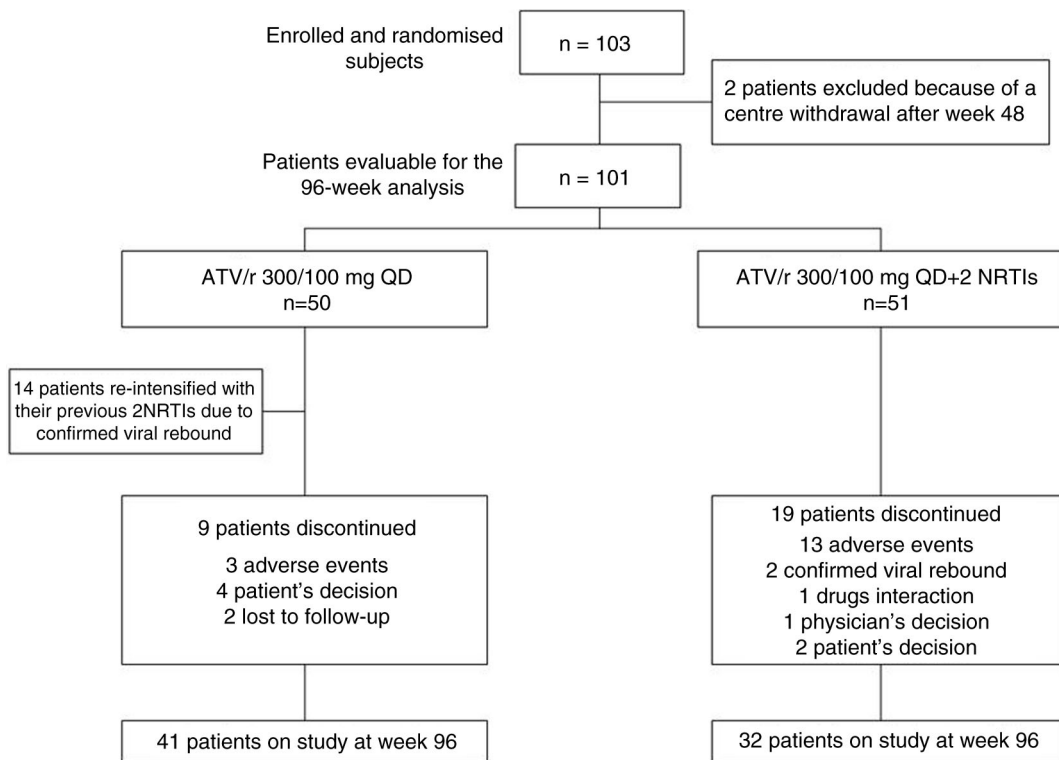
**Materials and Methods:** Multicentre, randomized, open-label, non-inferiority trial (non-inferiority margin –10%). Treatment failure (TF) was defined as CVF (two consecutive HIV-RNA >50 cp/mL) or discontinuation for any cause. In the monotherapy arm, patients with CVF re-introduced their previous NRTIs and remained in the study if HIV-RNA <50 copies/mL within 12 weeks of re-intensification.

**Results:** 101 patients evaluated (Figure 1): 85% males, 21% HCV-positive, median (IQR) age of 42 (36–48) years, baseline CD4 + 576 (447–743) cells/ $\mu$ L. In the 96-week analysis (ITT; TF = failure), efficacy was 64% (32/50) in the monotherapy arm and 63% (32/51) in the triple-therapy arm (difference +1.3%, 95% CI –17.5–20.1). Fourteen patients in monotherapy and two in triple-therapy arm had CVF; median HIV-RNA was 136 (72–376) copies/mL. In monotherapy arm, no PI or NRTI associated resistance mutations were observed at CVF. All patients who re-intensified re-suppressed. In monotherapy arm, TF was more frequent in HCV-co-infected patients (64% vs 28%;  $p=0.041$ ). In the secondary analysis (ITT; re-intensification = success), 82% (41/50) in monotherapy arm and 63% (32/51) in triple-therapy arm were on study at week 96 (difference +19.3%, 95% CI 2.2–36.3). SAEs occurred in four (8%) patients in the monotherapy arm (one left basal pneumonia, one acute coronary stenosis, one traumatic lesion, one nephrolithiasis) and two (4%) in the triple therapy arm (one sepsis, one renal failure). Drug-related adverse events (AEs) leading to discontinuation were three (6%) in the monotherapy arm (two AEs occurred in patients after successful re-intensification) and 12 (23.5%) in the triple-therapy ( $p=0.023$ ).

**Conclusions:** Despite the small sample size, the primary 96-week analysis showed that simplification to ATV/r monotherapy showed inferior efficacy to maintaining ATV/r triple-therapy but appeared to be superior when re-intensification was considered success.

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**Figure 1. The MODAT trial: 96-week patients disposition.**