Abstracts of the HIV Drug Therapy Glasgow Congress 2014
Spagnuolo V et al. *Journal of the International AIDS Society* 2014, **17(Suppl 3)**:19806
http://www.jiasociety.org/index.php/jias/article/view/19806 | http://dx.doi.org/10.7448/IAS.17.4.19806

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

Spagnuolo, Vincenzo[1]; Galli, Laura[1]; Bigoloni, Alba[1]; Nozza, Silvia[1]; d'Arminio Monforte, Antonella[2]; Antinori, Andrea[3]; Di Biagio, Antonio[4]; Rusconi, Stefano[5]; Guaraldi, Giovanni[6]; Di Giambenedetto, Simona[7]; Lazzarin, Adriano[1] and Castagna, Antonella[1]

[1]Department of Infectious Diseases, IRCCS San Raffaele Hospital, Milan, Italy. [2]Clinic of Infectious and Tropical Diseases, S Paolo Hospital, University of Milan, Milan, Italy. [3]Clinical Department, National Institute for Infectious Diseases IRCCS Lazzaro Spallanzani, Rome, Italy. [4]Division of Infectious Diseases, Azienda Ospedaliera San Martino, Genoa, Italy. [5]Division of Infectious Diseases, Ospedale Luigi Sacco, University of Milan, Milan, Italy. [6]Department of Medical and Surgical Sciences, University of Modena and Reggio Emilia, Modena, Italy. [7]Institute of Clinical Infectious Diseases, Catholic University of the Sacred Heart, Rome, Italy.

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/μL. 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.

Published 2 November 2014

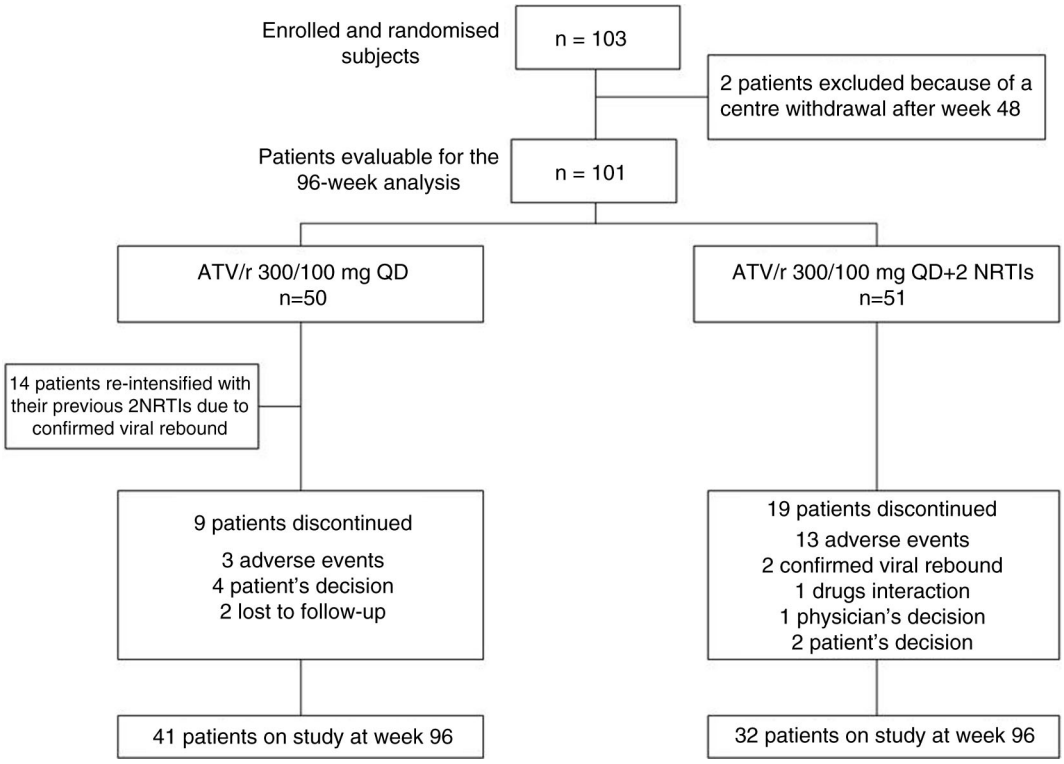

Figure 1. The MODAT trial: 96-week patients disposition.