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## EVALUATION OF RITONAVIR/SAQUINAVIR-BASED REGIMENS IN THE PREVENTION OF MTCT OF HIV

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**BACKGROUND:** Subtherapeutic levels of protease inhibitors (PI) in pregnancy at standard dosing have been reported. We previously identified significant (45%) failure of complete virological suppression using combivir/nelfinavir (standard doses) to prevent mother-to-child transmission (MTCT) of HIV. This study aims to evaluate the virological response, tolerability, and outcome in a cohort of pregnant women comparing combivir/saquinavir (SQV) (500 mg x 2)/ritonavir (RTV) (100 mg x 1) twice daily with combivir/nelfinavir (NFV) (standard doses).

**METHODS:** In the third trimester, 65 pregnant women were prescribed ART: 17 received combivir/RTV/SQV, while 48 received combivir/NFV. All received at least 6 weeks' treatment (range 6 to 12 weeks, mean 11 weeks) and discontinued postpartum. Genotypic resistance testing was performed 6 weeks postpartum. We then compared the viral load at 36 weeks' gestation between the 2 groups. In the combivir/RTV/SQV group, 1 went into premature labor and had her baby at 35 weeks.

**RESULTS:** Viral load at 36 weeks: in the combivir/RTV/SQV group, 14 of 16 (87.5%) <50 copies/mL, 2 of 16 (12.5%) had >50 <200 copies/mL;(mean 137copies/mL) compared with the combivir/NFV arm, in which 27 of 48 (56.2%) had <50 copies/mL, 18 of 48 (37.5%) >50 but <1000 copies/mL;(mean 154 copies/mL), and 3 of 48 (6.25%) >1000 copies/mL (mean 2160 copies/mL.) at 36 weeks. In the RTV/SQV cohort the mean pre-treatment viral load was 18,915copies/mL in the <50 group and 12,487 copies/mL in the >50 group, compared with the NFV cohort, whose mean pre-treatment viral load was 3761 copies/mL in the <50 group and 39,535 copies/mL in the >50 group. By the Fisher exact test, there was a significant association of viral suppression in the combivir/RTV/SQV group as compared with the combivir/NFV group ( $p < 0.01$ ). Adherence issues were identified in the NFV cohort in 4 of the 26 (15%) with 36-week viral load of <50 copies/mL;1 of 18 (5.5%) with a viral load of >50 but <1000

copies/mL and 1 of 3 (33%) with a viral >1000 copies/mL. No adherence issues were identified in the RTV/SQV cohort, however 1 patient was interchanged to NFV after 10 days because of severe vomiting associated with RTV/SQV, and this was included in the NFV data. This is an ongoing study, and pharmacokinetic tests are being performed routinely on 6 new patients who have recently been admitted to the study. Genotypic resistance was possible in 41 of 73 patients 6 weeks postpartum. No primary PI resistance mutations were identified after treatment cessation. In the combivir/NFV group, 1 baby acquired HIV (maternal viral load was <50 copies/mL, membranes ruptured >24 hours).

<b>Viral load @ 36 weeks</b>	<b>RTV/SQV</b>	<b>NFV</b>
Viral load <50	14/16 (87.5%)	27/48 (56.2%)
Viral load >50 but <1000	2/16 (12.5%) mean 137 copies/mL	18/48 (37.5%) mean 154 copies/mL
Viral load >1000	nil	3/48 (6.25%) mean 2160 copies/mL

**CONCLUSIONS:** Treatment with combivir/RTV/SQV achieved better virological suppression than combivir/NFV, and this was significant ( $p < 0.01$ ), supporting previous studies of superior pharmacokinetics in pregnancy with RTV/SQV viral loads than with NFV. However the absence of PI mutations in either group post-treatment suggests that short-term treatment with either PI has no apparent detrimental effect on future ART options.

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