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# Safety and efficacy of lopinavir/ritonavir compared to nelfinavir-based HAART during pregnancy

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#### Purpose of the study

To compare the safety and efficacy of lopinavir/ritonavir and nelfinavir-based regimens in HIV-1 infected pregnant women.

#### Methods

A prospective cohort study to evaluate HIV mother-tochild transmission. The study took place at 13 Spanish hospitals. We reviewed the records of all pregnant women treated with NFV (NCR) or LOP/r-containing (LOP/r CR) regimens during pregnancy from May 2001 to December 2007. Drug selection was up to the physician. Abnormalities were graded according to the National Institute of Allergy and Infectious Disease Division of AIDS toxicity guidelines. Data of mother and their children were recorded following a standard protocol.

#### Summary of results

355 mothers were enrolled: mean age 31 years; Caucasian 74%; HCV co-infection 34%; 13% were on C3 according to CDC category; heterosexual transmission 64%. 40% received antiretroviral therapy for the first time during pregnancy. 121 (34%) were on LOP/r CR and 234 (66%) on NCR. Baseline characteristics, side-effects and discontinuation of LPV or NFV of both groups are shown in Table 1 (values are expressed as the median [IQR] for continuous variables and as N [%] for categorical variables).

No aminotransferases abnormalities (grade 3–4) or clinical hepatitis were observed. There were no differences in both groups according to weight and gestational age of the babies at delivery. There was a case of vertical transmission (a mother treated with NFV and viral load above 500,000 copies/ml).

#### Conclusion

In our cohort lopinavir/ritonavir and nelfinavir-based regimens during pregnancy were safe, effective and well tolerated.

#### Table I:

	NELFINAVIR	LOPINAVIR/RITONAVIR	Р
Age (yr)	32 (28–36)	32 (26–36)	NS
C3 category	21 (10)	21 (19)	0,026
CD4 (cells/µL) at 1st visit	477 (325-652)	426 (264–600)	NS
Viral load < 50 copies/ml at 3rd trimester	142 (70)	61 (62)	NS
Hepatitis C	79 (35)	40 (33)	NS
HAART-naive patients	108 (48)	35 (29)	0.001
Gestational diabetes mellitus	15 (8)	5 (5)	NS
Vomiting	9 (4)	16 (14)	<0.001
Diarrhoea	27 (12)	15 (14)	NS
Discontinuation of LPV or NFV.	23 (10)	12 (10)	NS
Discontinuation of LPV or NFV due to virologic failure.	I (0.4)	I (0.8)	NS
Vertical transmission	I (0.4)	0	NS

