



# Pregnancy Outcomes of Women Receiving Efavirenz after the First Trimester.

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## Background:

While efavirenz (EFV) is generally not recommended for use during early pregnancy or for women unable to secure adequate contraception, EFV is nonetheless prescribed for these populations, particularly when nevirapine (NVP)-related toxicities occur. This study reports on the experience of using EFV after the first trimester among HIV-infected pregnant women.

## Methods:

The MTCT-Plus Initiative has given AZT/3TC/NVP to Thai HIV-infected pregnant women in the program who had CD4 count <200 cells/mm<sup>3</sup> since February 2003. Since April 2004, the Thai Red Cross AIDS Research Centre (TRCARC) has also provided AZT/3TC/NVP to all pregnant women, started from 14 weeks of gestation if CD4 count <200 cells/mm<sup>3</sup> and from 28 weeks if >200 cells/mm<sup>3</sup>. AST/ALT was checked at baseline, week 2, 4, 6, 8 and then every 4 weeks until delivery. NVP was stopped if toxicities ≥grade II occurred and substituted by EFV or PI. Data were retrieved from all pregnant women who received HAART during pregnancy and were followed until delivery by September 2006.

## Results:

Among 606 pregnant women who received HAART in this period, 38 women needed to use EFV during pregnancy due to toxicities from NVP. Mean age at pregnancy was 28±5.4 years. Mean time of EFV exposure was 7 weeks (4 days-19 weeks) and no one was exposed to EFV in the first trimester. There were 38 pregnancy outcomes with male to female ratio of 1:1.2. Preterm birth (<37 weeks of gestation) was found in 4 (10.5%) and 6 (15.8%) had low birth weight (LBW <2,500 g).

These rates were not higher than those observed among 553 pregnant women on NVP-based regimen in the same cohort (18.5% preterm birth P=0.295, 16.0% LBW P=0.639). **All infants were found healthy at birth and no congenital anomaly was observed.** One infant died at day 18 due to aspiration pneumonia.

### Characteristics and pregnancy outcomes of 38 women receiving efavirenz.

Characteristics	Result
Age (mean ± SD)	28±5.4
Time of EFV exposure (weeks, mean ±SD)	7±4.9
GA at the start of EFV (weeks, mean ±SD)	33.2±4.9
Male:female infant	1:1.2
Preterm birth (N, %)	4 (10.5%)
Low birth weight (N, %)	6 (15.8%)

## Conclusions:

- EFV use after the first trimester was found relatively safe among these 38 Thai pregnant women.
- No congenital anomaly was observed and rates of preterm birth and low birth weight were similar to those who received NVP-based regimen in the same cohort.
- Monitoring of pregnancy outcomes in larger population should be continued as this would provide important information to support recommendations in international guidelines for EFV use in the second and third trimesters of pregnancy whenever necessary.