

**TABLE 2: SUMMARY OF SELECTED CLINICAL TRIALS OF PROPHYLACTIC ARV REGIMENS FOR PMTCT<sup>1</sup>**

Study (location)	Drugs	Antenatal/ Intrapartum	Postpartum	Median Maternal CD4+ T Cell Count by Arm at Enrollment	Mode of Infant Feeding	Vertical Transmission Rate (VTR) and Efficacy
PACTG 076/ANRS 024 Trial USA; France	ZDV vs. placebo	Long (from 14 weeks), IV intrapartum	Long (6 weeks) (infant only)	538, 560	Formula	VTR 7.6% in intervention arm vs. 22.6% in placebo arm at 18 months (68% efficacy)
Bangkok CDC Short-Course ZDV Trial Thailand	ZDV vs. placebo	Short (from 36 weeks), oral intrapartum	None	411, 427	Formula	VTR 9.4% in intervention arm vs. 18.9% in placebo at 6 months (50.1% efficacy)
Thai Perinatal HIV Prevention Trial Thailand	ZDV different regimens, no placebo	Long (from 28 weeks), short (from 36 weeks)	Long (for 6 weeks), short (for 3 days) (infant only)	350, 380	Formula	Short-short arm was stopped (VTR 11%). VTR 6.5% in long-long arm vs. 4.7% in long-short arm and 8.6% in the short-long arm at 6 months (statistical equivalence) <i>In utero</i> transmission significantly higher with short compared to long maternal therapy regimens (5.1% vs. 1.6%)
Côte d'Ivoire CDC Short-Course ZDV Trial Côte d'Ivoire	ZDV vs. placebo	Short (from 36 weeks)	None	528, 548	Breast	VTR 15.7% in intervention arm vs. 24.9% in placebo at 3 months (37% efficacy)
DITRAME/ANRS 049a Trial Côte d'Ivoire; Burkina Faso	ZDV vs. placebo	Short (from 36 weeks)	Short (1 week) (mother only)	535, 568	Breast	VTR 18.0% in ZDV arm, 27.5% in placebo at 6 months (38% efficacy); 21.5% vs. 30.6% (30% efficacy) at 15 months; 22.5% vs. 30.2% (26% efficacy) in pooled analysis with other Côte d'Ivoire trial at 24 months
PETRA Trial South Africa; Tanzania; and Uganda	ZDV + 3TC in 3 regimens vs. placebo	Short (from 36 weeks)	Short (7 days) (mother and infant)	435, 475	Breast	VTR 5.7% at 6-8 weeks for antenatal/intrapartum/neonatal ZDV + 3TC, 8.9% for intrapartum/neonatal ZDV + 3TC, 14.2% for intrapartum ZDV + 3TC only, and 15.3% for placebo (efficacy compared to placebo, 63%, 42%, and 0%, respectively) VTR 14.9% at 18 months for antenatal/intrapartum/neonatal ZDV + 3TC, 18.1% for intrapartum/neonatal ZDV + 3TC, 20.0% for intrapartum ZDV + 3TC only and 22.2% for placebo

<sup>1</sup> Adapted from: World Health Organization. Antiretroviral drugs for treating pregnant women and prevention HIV infection in infants: guidelines on care, treatment and support for women living with HIV/AIDS and their children in resource-constrained settings. Geneva, 2004.

Study (location)	Drugs	Antenatal/ Intrapartum	Postpartum	Median Maternal CD4+ T Cell Count by Arm at Enrollment	Mode of Infant Feeding	Vertical Transmission Rate (VTR) and Efficacy
						(efficacy compared to placebo, 34%, 18%, and 0%, respectively)
French ZDV + 3TC/ANRS 075 Trial France	Open label, non-randomised ZDV + 3TC	ZDV (from 14 weeks) with 3TC added at 32 weeks	3TC and ZDV for 6 weeks (infant only)	426	Formula	VTR 1.6%; 5x lower than in historical controls receiving ZDV only
Thai ZDV + 3TC Trial Thailand	Open label, non-randomised ZDV + 3TC	Short (from 34 weeks)	Long (ZDV, 4 weeks) (infant only)	274	Formula	VTR 2.8% at 18 months
PACTG 316 Trial (USA; Europe; Brazil; Bahamas)	NVP vs. placebo in women already receiving ZDV or ZDV plus other ART	Non-study ART antenatal. Intrapartum: SD NVP 200mg plus ZDV continuous infusion IV	SD 2mg/kg within 72 hours of birth plus non-study ART including 6 weeks ZDV (infant only)	423, 441	Formula	77% women received combination ARV during pregnancy Trial stopped early due to very low VTR in both arms VTR 1.4% in intervention arm vs. 1.6% in placebo arm
HIVNET 012 Trial Uganda	NVP vs. ZDV	No antenatal ART Intrapartum: SD NVP 200mg vs. oral ZDV	SD NVP 2mg/kg within 72 hours of birth vs. short ZDV (7 days) (infant only)	426, 461	Breast	Placebo arm was stopped VTR 13.1% in NVP arm vs. 25.1% in ZDV arm (47% efficacy) at 14-16 weeks VTR 15.7% in NVP arm vs. 25.8% in ZDV arm (41% efficacy) at 18 months
SAINT Trial South Africa	NVP vs. ZDV + 3TC	No antenatal ART Intrapartum: SD NVP 200mg vs. ZDV + 3TC	SD NVP within 48 hours of birth (infant only) vs. short ZDV + 3TC (7 days) (mother and infant)	384, 404	Breast (42%) and formula	VTR 12.3% in NVP arm vs. 9.3% in ZDV + 3TC arm at 8 weeks (not significantly different)
DITRAME Plus/ANRS 1201.0 Trial Abidjan, Côte d'Ivoire	Open label, ZDV boosted by SD NVP	ZDV from 36 weeks, NVP one dose at onset of labour	SD NVP, plus one week ZDV (infant only)	370	Breast (50%) and formula	VTR 6.4% at 6 weeks
DITRAME Plus/ANRS 1201.1 Trial Abidjan, Côte d'Ivoire	Open label, ZDV + 3TC boosted by SD NVP	ZDV + 3TC from 32 weeks (stopped at day 3)	SD NVP, plus one week ZDV (infant only)	439	Breast and formula	VTR 4.6% at 6 weeks

Study (location)	Drugs	Antenatal/ Intrapartum	Postpartum	Median Maternal CD4+ T Cell Count by Arm at Enrollment	Mode of Infant Feeding	Vertical Transmission Rate (VTR) and Efficacy
		postpartum), SD NVP at onset of labour				
Thai Perinatal HIV Prevention Trial-2 Thailand	ZDV alone vs. ZDV plus mother/infant NVP vs. ZDV plus mother NVP	ZDV from 28 weeks and intrapartum Intrapartum: ZDV alone or plus SD NVP at onset of labour	One week ZDV with or without SD NVP (infant only)		Formula	ZDV alone arm was stopped due to higher transmission rate than maternal/infant NVP arm (VTR 6.3% vs. 1.1%) Final result comparing two NVP arms: VTR not significantly different when infant received vs. did not receive SD NVP (2.0% vs. 2.8%).
SIMBA Trial Rwanda; Uganda	NVP vs. 3TC postnatally in neonates exposed antenatally and 1 week postpartum to ZDV + ddi	ZDV + ddi from 36 weeks and given intrapartum	ZDV + ddi for 1 week (mother only), SD NVP then b.i.d vs. 3TC b.i.d while breastfeeding (infant only)	423, 432	Breast (median duration 3.4 months, inter-quartile range: 2.9–5.1 months)	VTR 7.8% at 6 months (no difference between the two arms). Transmission rate between 4 days and 6 months of age: 2.4% (1.0% between 1 and 6 months)
NVAZ Trial (late presenters–no maternal SD NVP) Malawi	Neonatal NVP vs. NVP + ZDV	None (latecomers)	SD NVP right after birth; ZDV b.i.d for 1 week (infant only)	Not reported	Breast	Overall VTR at 6-8 weeks 15.3% in NVP + ZDV arm and 20.9% with NVP only. VTR at 6-8 weeks in infants who were negative at birth 7.7% and 12.1%, respectively (36% efficacy)
NVAZ Trial (early presenters–mothers got SD NVP) Malawi (JAMA)	Neonatal NVP vs. NVP + ZDV	SD NVP intrapartum	SD NVP right after birth; ZDV b.i.d for 1 week (infant only)	Not reported	Breast	Overall VTR at 6-8 weeks 16.3% in NVP + ZDV arm and 14.1% with NVP only. VTR at 6-8 weeks in infants who were negative at birth 6.9% and 6.5% respectively (no efficacy)