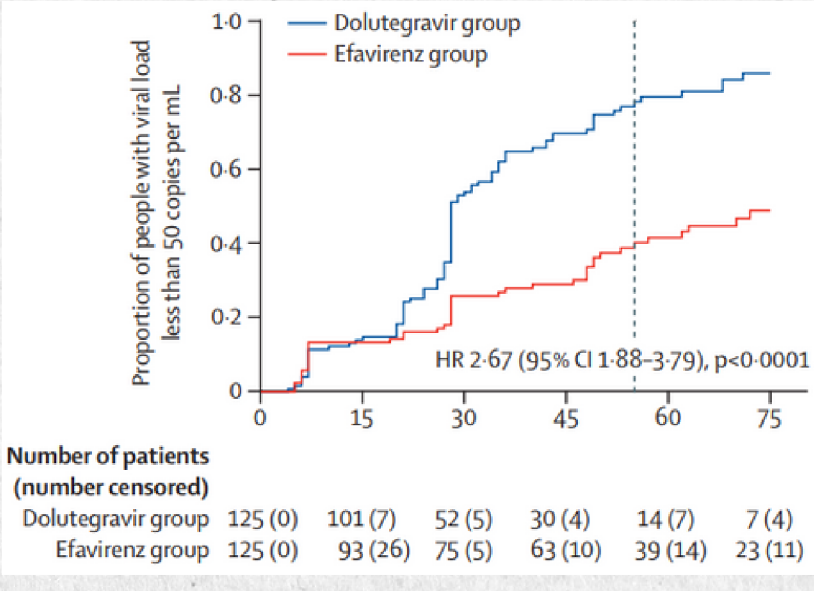
Dol PHINE-2

Open-label trial randomised pregnant women initiating cART in 3rd trimester to either DTG or EFV-based regime in South Africa and Uganda, with 72 weeks post-partum follow-up

Primary endpoint

At 72 weeks postpartum,median time to VL < 50 was 4.1 weeks (DTG) vs 12.1 weeks (EFV) (aHR 1.93). Similar findings observed in VL <1K, 1 vs 3.7 weeks (DTG vs EFV)



	Total	Dolutegravir group	Efavirenz group
Mothers			
Number of mothers	268	135	133
Serious adverse events			
Overall (pregnancy and postpartum events)			
1 or more serious adverse event	57 (21%)	33 (24%)	24 (18%)
Serious adverse event grade ≥3	49 (18%)	28 (21%)	21 (16%)
1 or more drug related serious adverse event	8 (3%)	3 (2%)	5 (4%)
Deaths	0	0	0
Postpartum events			
1 or more serious adverse event	21 (8%)	9 (7%)	12 (9%)
Serious adverse event grade ≥3	19 (7%)	8 (6%)	11 (8%)
1 or more drug related serious adverse event	7 (3%)	2 (2%)	5 (4%)
System organ class			
Blood and lymphatic system disorders	3 (1%)	2 (2%)	1 (1%)
Gastrointestinal disorders	1 (<1%)	1 (1%)	0
Infections and infestations	11 (4%)	7 (5%)	4 (3%)
Pregnancy, puerperium, and perinatal conditions excluding stillbirths	24 (9%)	15 (11%)	9 (7%)
Renal and urinary disorders	3 (1%)	2 (2%)	0
Vascular disorders	1 (<1%)	0	1 (1%)

Secondary endpoint

- **Maternal safety- described in 2nd table**
- **Infant safety- nil side effects in both groups**
- **MTCT- 3 in-utero transmission (DTG arm) and 1 postpartum transmission (EFV arm) with exclusive breastfeeding**

Summary

1. Both regimens were safe and well-tolerated
2. DTG-based regimen had superior virologic efficacy
3. Infant HIV infection in EFV arm highlights potential for transmission during breastfeeding in women

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