GRADE table: What ARV regimen to start (once-daily NNRTI regimens) for pregnant women living with HIV?

Author(s): George W. Rutherford, Alicen B. Spaulding
Date: 2012-09-28
Question: TDF/FTC/EFV versus ZDV/3TC/EFV for initial treatment of HIV infection
Settings: Multiple high-income and low- and middle-income country settings
Bibliography: Arribas 2008, Avihingsanon 2010, Campbell 2012, Pozniak 2006.

Quality assessment							No. of patients		Effect		Quality	Importance
No. of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TDF/FTC/EFV	ZDV/3TC/EFV	Relative (95% CI)	Absolute		
Mortality (96 weeks)												
1	randomized trials	no serious risk of bias[1,2]	no serious inconsistency	serious indirectness[3]	very serious imprecision[4]	none	2/258 (0.78%)	2/259 (0.77%)	RR 1 (0.14 to 7.07)	0 fewer per 1000 (from 7 fewer to 47 more)	⊕OOO VERY LOW	CRITICAL
Mortality (median 184 weeks)												
1	randomized trials	no serious risk of bias	no serious inconsistency	serious indirectness[3]	very serious imprecision[4]	none	18/525 (3.4%)	20/517 (3.9%)	RR 0.89 (0.47 to 1.66)	4 fewer per 1000 (from 21 fewer to 26 more)	⊕OOO VERY LOW	CRITICAL
Disease progression (median 184 weeks)												
1	randomized trials	no serious risk of bias	no serious inconsistency	serious indirectness[3]	very serious imprecision[4]	none	10/525 (1.9%)	15/517 (2.9%)	RR 0.66 (0.3 to 1.45)	10 fewer per 1000 (from 20 fewer to 13 more)	⊕OOO VERY LOW	CRITICAL
Serious adverse events (median 184 weeks)												
1	randomized trials	no serious risk of bias	no serious inconsistency	serious indirectness[3]	serious imprecision[7]	none	116/525 (22.1%)	115/517 (22.2%)	RR 0.99 (0.79 to 1.25)	2 fewer per 1000 (from 47 fewer to 56 more)	⊕⊕⊕O MODERATE	CRITICAL
Viral response (<400 copies/ml) (144 and 183 weeks)												

This work was commissioned by the World Health Organization and carried out by The University of California, San Francisco (UCSF), Cochrane Review Group on HIV/AIDS

2	randomized trials	no serious risk of bias[1,2]	no serious inconsistency	serious indirectness[3]	no serious imprecision	none	581/783 (74.2%)	624/776 (80.4%)	RR 1.01 (0.67 to 1.52)	8 more per 1000 (from 265 fewer to 418 more)	⊕⊕⊕O MODERATE	CRITICAL
Immune response (48 weeks) (better indicated by higher values)												
1	randomized trials	no serious risk of bias[1,5]	no serious inconsistency	serious indirectness[3]	very serious imprecision[6]	none	10	6	-	Mean difference 72 higher (79.82 lower to 223.82 higher)	⊕⊕OO LOW	CRITICAL
Immune response (144 and 183 weeks) (better indicated by higher values)												
2	randomized trials	no serious risk of bias[1,2]	no serious inconsistency	serious indirectness[3]	no serious imprecision	none	783	776	–	Mean difference 17.05 higher (27.99 lower to 62.09 higher)	⊕⊕⊕O MODERATE	CRITICAL
Retention on treatment (96 weeks)												
1	randomized trials	no serious risk of bias[1,2]	no serious inconsistency	serious indirectness[3]	no serious imprecision	none	232/258 (89.9%)	231/259 (89.2%)	RR 1.01 (0.95 to 1.07)	9 more per 1000 (from 45 fewer to 62 more)	⊕⊕⊕O MODERATE	CRITICAL
Retention on treatment (median 184 weeks)												
1	randomized trials	no serious risk of bias	no serious inconsistency	serious indirectness[3]	no serious imprecision	none	444/526 (84.4%)	418/517 (80.9%)	RR 1.04 (0.99 to 1.1)	32 more per 1000 (from 8 fewer to 81 more)	⊕⊕⊕O MODERATE	CRITICAL
Switching (96 weeks)												
1	randomized trials	no serious risk of bias[1,2]	no serious inconsistency	serious indirectness[3]	very serious imprecision[4]	none	2/232 (0.86%)	2/231 (0.87%)	RR 1 (0.14 to 7.01)	0 fewer per 1000 (from 7 fewer to 52 more)	⊕OOO VERY LOW	CRITICAL

[1] Two studies (three publications) funded by industry.
[2] Three of four studies open-label.
[3] No studies included pregnant women.
[4] Very few events
[5] One non-blinded study.
[6] Very small sample size.
[7] Few events.

This work was commissioned by the World Health Organization and carried out by The University of California, San Francisco (UCSF), Cochrane Review Group on HIV/AIDS