BREATHER (PENTA 16) short-cycle therapy (SCT) (5 days on/2 days off) in young people with chronic human immunodeficiency virus infection: an open, randomised, parallel-group Phase II/III trial

Record Status
This is a bibliographic record of a published health technology assessment from a member of INAHTA. No evaluation of the quality of this assessment has been made for the HTA database.

Citation

Authors' objectives
To determine whether or not efavirenz (EFV)-based ART in short cycles of 5 days on and 2 days off is as efficacious (in maintaining virological suppression) as continuous EFV-based ART (continuous therapy; CT). Secondary objectives included the occurrence of new clinical HIV events or death, changes in immunological status, emergence of HIV drug resistance, drug toxicity and changes in therapy.

Authors' conclusions
Non-inferiority of VL suppression in young people on EFV-based first-line ART with a VL of < 50 copies/ml was demonstrated for SCT compared with CT, with similar resistance, safety and inflammatory marker profiles. The SCT group had fewer ART-related adverse events. Further evaluation of the immunological and virological impact of SCT is ongoing. A limitation of the trial is that the results cannot be generalised to settings where VL monitoring is either not available or infrequent, nor to use of low-dose EFV. Two-year extended follow-up of the trial is ongoing to confirm the durability of the SCT strategy. Further trials of SCT in settings with infrequent VL monitoring and with other antiretroviral drugs such as tenofovir alafenamide, which has a long intracellular half-life, and/or dolutegravir, which has a higher barrier to resistance, are planned.

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