**DART: DESIGN and REGIMENS**

DART is a large randomised trial with clinical endpoints, primarily assessing whether ART can be given safely without routine laboratory monitoring for toxicity (haematology, biochemistry) and efficacy (CD4 count monitoring).

- **Methods**
  - 300 patients receive triple ART
  - viral load monitoring is not performed in any patient
  - 2486 (74%) have received zidovudine + lamivudine (as combivir) plus tenofovir DF

**OBJECTIVES**

1. To determine response to ZDV+3TC+TDF through 48 weeks
2. To describe emergence of resistance mutations in those with HIV-1 RNA ≥1000 copies/ml at 24 weeks

**METHODS**

- 300 patients
  - 100 from each of 3 sites: 2 in Uganda and 1 in Zimbabwe
  - half with baseline CD4 ≥1000 cells/mm³
  - consecutive patients enrolled in each CD4 strata (99-100 and 100-1000 cells/mm³) after the first 2 months of the trial, excluding the first 20 patients in each site
  - 77 of the original 300 patients entered a pilot STI study at 24 weeks (based on their week 24 CD4 response) and interrupted ART for 12 weeks
  - excluded and replaced with patients matched on baseline and week 24 CD4 who did not interrupt ART

**Viral load response**

- Plasma HIV-1 RNA assessed on stored specimens at 0, 4, 12, 24, 36 and 48 weeks after ZDV+3TC+TDF initiation
- Samples >1000 c/ml at 24 weeks (from the initial week 24 population) were sequenced

**POPULATION CHARACTERISTICS (n=300)**

- **Sex**: 66% women
- **Age**: median 37.3 years (range 20-62 years)
- **CD4**: median 100 cells/mm³, 50% ≥50 cells/mm³
- **WHO stage**: 2.3% (23%), 3 (51%), 4 (25%)
- **HIV RNA**: median 279,910 c/ml
- **231 (77%) patients known to be alive at week 48 having been given a diagnosis of HIV in the absence of treatment interruption
- **17 (6%) patients had substituted D4T for ZDV
- **38 (13%) patients interrupted ART for 3 days (median 12 days, range 4-187 days)**

**CHANGE in HIV-1 RNA and CD4**

- **Weeks from initiation of ZDV+3TC+TDF**
- **Mean increase in CD4 cells (×10³)**
  - 200
  - 283
  - 271
  - 284
  - 272
  - **Mean increase in HIV-1 RNA (log10 c/ml)**
  - 0.1
  - 0.0
  - 0.1
  - 0.0
  - 0.0

**Viral loads and patient status over time**

- **Viral suppression at 48 weeks**: 77/74% of the original 300 patients entered a pilot STI study at 28 weeks (based on their week 24 CD4 response) and 77 of them (range 1-4) had continued ART for 48 weeks

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