**Supplementary material**

Appendix Table 1. Baseline Characteristics of participants eligible for per-protocol analyses, START trial 2009-2015.

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|  | **All participants (N=4676)** | **Immediate ART initiation (N=2321)** | **Deferred ART initiation (N=2355)** |
| **Characteristics** |  |  |  |
| Median age (IQR), years | 36 (29,44) | 36 (29,44) | 36 (29,44) |
| Median CD4 count (IQR), cells/mm3 | 651 (584,765) | 652 (585,765) | 651 (582,764) |
| Median HIV RNA (IQR), copies/mL | 12756 (3019,43391) | 13000 (3133,43808) | 12550 (2963,42567) |
| Median time since HIV diagnosis (IQR), years | 1.0 (0.4,3.0) | 1.0 (0.3,3.0) | 1.1 (0.4,3.1) |
| Ethnic group, N (%) |  |  |  |
| Black | 1409 (30.1) | 701 (30.2) | 708 (30.1) |
| Hispanic | 637 (13.6) | 319 (13.7) | 318 (13.5) |
| Asian | 385 (8.2) | 196 (8.4) | 189 (8.0) |
| White | 2082 (44.5) | 1014 (43.7) | 1069 (45.4) |
| Other | 163 (3.5) | 91 (3.9) | 72 (3.1) |
| Mode of infection with HIV, N (%) |  |  |  |
| Injection drug use | 64 (1.4) | 37 (1.6) | 27 (1.2) |
| Sexual contact |  |  |  |
| Men having sex with men | 2581 (55.2) | 1298 (55.9) | 1283 (54.5) |
| With person of opposite sex | 1787 (38.2) | 871 (37.5) | 916 (38.9) |
| Blood products, other, or unknown | 244 (5.2) | 115 (5.0) | 129 (5.5) |
| Geographical region, N (%) |  |  |  |
| Africa | 999 (21.4) | 498 (21.5) | 501 (21.3) |
| Asia | 353 (7.6) | 177 (7.6) | 176 (7.5) |
| Europe and Israel | 1536 (32.9) | 763 (32.9) | 773 (32.8) |
| North America | 505 (10.8) | 246 (10.6) | 259 (11.0) |
| Oceania | 109 (2.3) | 56 (2.4) | 53 (2.3) |
| South America and Mexico | 1174 (25.1) | 581 (25.0) | 593 (25.2) |
| Sex, N (%) |  |  |  |
| Male | 3423 (73.2) | 1700 (73.2) | 1723 (73.2) |
| Female | 1253 (26.8) | 621 (26.8) | 632 (26.8) |

Appendix Table 2. Baseline and post-randomization factors associated with ART initiation after randomization in 2321 participants in the immediate ART initiation group and in 2355 participants in the deferred ART initiation group. START trial 2009-2015.

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| --- | --- | --- | --- | --- |
|  | **Hazard ratios of ART initiation (95% CI)** | | | |
|  | **Immediate ART initiation group (N=2321) §** | | **Deferred ART initiation group (N=2355) §** | |
| Sex |  |  |  |  |
| Female | 1.24 | (1.00,1.53) | 0.95 | (0.80,1.13) |
| Male | Ref |  | Ref |  |
| Geographical area |  |  |  |  |
| High income region | 0.88 | (0.73,1.05) | 1.84 | (1.60,2.13) |
| Low-mid income region | Ref |  | Ref |  |
| CD4 count at randomization, cells/mm3 | | |  |  |
| <650 | 2.20 | (1.09,4.55) | 1.06 | (0.92,1.23) |
| ≥650 | Ref |  | Ref |  |
| HIV-RNA at randomization, copies/mL | | |  |  |
| <5000 | 2.07 | (0.87,4.94) | 0.74 | (0.62,0.89) |
| ≥5000 | Ref |  | Ref |  |
| Age at randomization, years | |  |  |  |
| <35 | 0.72 | (0.61,0.86) | 1.31 | (1.14,1.50) |
| ≥35 | Ref |  | Ref |  |
| Post randomization CD4 count, cells/mm3 | | |  |  |
| <650 | 1.04 | (0.37,2.90) |  |  |
| ≥650 | Ref |  |  |  |
| Post randomization CD4 count, cells/mm3 | | |  |  |
| <350 |  |  | 24.15 | (19.25,30.31) |
| 350-650 |  |  | 1.58 | (1.30,1.92) |
| ≥650 |  |  | Ref |  |
| Post randomization HIV-RNA, copies/mL | | |  |  |
| <5000 | 0.43 | (0.18,1.02) | 0.65 | (0.52,0.80) |
| ≥5000 | Ref |  | Ref |  |
| Time since the last laboratory measurement, months | |  |  |  |
| ≤4 | 10.22 | (5.30,19.7) | 4.73 | (3.47,6.46) |
| >4 | Ref |  | Ref |  |

§ 2276 participants started ART in the immediate ART initiation group and 1045 participants started ART in the deferred ART initiation group.

Appendix Table 3. Per-protocol estimates of risk at 3 and 5 years for the sensitivity analyses. START trial 2009-2015.

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| --- | --- | --- | --- | --- |
|  | **Risk (95% CI) at 3 years** | | **Risk (95% CI) at 5 years** | |
| Sensitivity analysis | **Immediate ART initiation** | **Deferred ART initiation** | **Immediate ART initiation** | **Deferred ART initiation** |
| *Main analysis* | 1.5 (1.0,2.0) | 4.1 (3.3,5.1) | 3.2 (2.0,4.6) | 7.0 (5.2,9.6) |
| *Two-month time window for ART initiation* | 1.5 (1.1,2.0) | 4.1 (3.4,5.1) | 3.2 (2.0,4.7) | 7.0 (5.2,9.2) |
| *Initiate ART at pregnancy in the deferred group* | 1.5 (1.0,2.0) | 4.1 (3.2,5.1) | 3.2 (2.0,4.6) | 7.0 (5.6,9.2) |
| *Censoring at 6 months after no CD4 count or HIV-RNA measurement* | 1.5 (0.6,2.1) | 4.2 (3.4,5.0) | 3.2 (1.6,4.8) | 7.1 (5.5,9.5) |
| *Censoring at 18 months after no CD4 count or HIV-RNA measurement* | 1.4 (1.0,2.0) | 4.1 (3.3,5.0) | 3.1 (1.9,4.3) | 7.3 (5.6,9.6) |

Appendix Figure 1 a. Mean of the outcome and time-varying variables in the immediate ART initiation group: observed (solid blue line) and simulated via the parametric g-formula assuming same adherence to the protocol as in the observed data (dashed red line).

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Appendix Figure 1b. Mean of the outcome and time-varying variables in the deferred ART initiation group: observed (solid blue line) and simulated via the parametric g-formula assuming same adherence to the protocol as in the observed data (dashed red line).

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