



Pros and Cons of Either Treatment Group

EARLY Group

PROS

Longer period of time at higher CD4+ cell counts

Possible protection from illnesses and complications of HIV and other causes

Decreased risk of transmitting the virus to others

CONS

More short-term and long-term side effects from HIV medicines

Higher risk that HIV medicines will not work over time because of resistance

Inconvenience of taking medicines earlier that may affect your lifestyle

DEFERRED Group

PROS

Delaying side effects from HIV medicines

Waiting for newer drugs that may be better and safer

Convenience of not taking HIV medicines all the time

CONS

Longer period of time at lower CD4+ cell counts and higher viral loads

Higher risk of AIDS and other illnesses

Increased risk of transmitting the virus to others



Eligibility

Inclusion Criteria

Signed informed consent

HIV infection documented by plasma HIV RNA viral load, a rapid HIV test or any licensed ELISA test; and confirmed by an ELISA, Western Blot, HIV culture, HIV antigen, HIV pro-viral DNA or a second antibody test by a method other than ELISA at any time prior to study entry

Age > 18 years

Karnofsky performance score \geq 80 (an indication that the participant can perform normal activities)

Perceived life expectancy of at least 6 months

For women of child-bearing potential, willingness to use contraceptives as described in the product information of the ART drugs they are prescribed

Two consecutive CD4+ cell counts > 500 cells/mm³ at least 2 weeks apart within 60 days before randomization

Exclusion Criteria

Any previous use of ART or IL-2

Diagnosis of any clinical AIDS event before randomization (including esophageal candidiasis and chronic Herpes simplex infection)

Presence of HIV progression such as oral thrush, unexplained weight loss, or unexplained fever

Cardiovascular event (myocardial infarction, angioplasty, coronary-artery bypass grafting, stroke) within 6 months before randomization

Non-AIDS-defining cancer, excluding basal and squamous cell skin cancer, within 6 months before randomization

Dialysis within 6 months before randomization

History of decompensated liver disease

Current imprisonment or compulsory detention (involuntary incarceration) for treatment of a psychiatric or physical illness

Current pregnancy or breastfeeding (a negative serum or urine pregnancy test is required within 14 days before randomization for women of child-bearing potential)