Darunavir/r Monotherapy versus Triple Therapy

PROTEA Trial
Darunavir/r Monotherapy versus Triple Therapy

PROTEA: Study Design

**Study Design: PROTEA Study**

- **Background**: Randomized, controlled, open label, phase 3b trial evaluate noninferiority of darunavir + ritonavir (monotherapy) versus darunavir + ritonavir + 2NRTIs (triple therapy) in virologically suppressed patients

- **Inclusion Criteria** (n = 273)
  - HIV RNA <50 copies/mL x 24 weeks on 3-drug ART
  - CD4 count >200 cells/mm³
  - CD4 count nadir >100 cells/mm³
  - No PI resistance or history of virologic failure

- **Treatment Arms**
  - Darunavir 800 mg QD + RTV 100 mg QD
  - Darunavir 800 mg QD + RTV 100 mg QD + 2 NRTIs

*Both arms: 4-week run-in with DRV + RTV + 2 NRTIs

Darunavir/r Monotherapy versus Triple Therapy
PROTEA: Result

Week 48: Virologic Response, by Statistical Efficacy Analyses

Darunavir/r Monotherapy versus Triple Therapy
PROTEA: Result

Week 48: Virologic Response, by Nadir CD4 Count

Darunavir/r Monotherapy versus Triple Therapy

**PROTEA: Result**

Week 48: Virologic Response, by Nadir CD4 Count

![Bar chart showing virologic response by CD4 nadir and treatment regimen.](chart.png)

Conclusions: “In this study for patients with HIV-1 RNA < 50 copies/mL at baseline, switching to DRV/r monotherapy showed lower efficacy versus triple antiretroviral therapy at Week 48 in the primary switch equals failure analysis (86% versus 95%). However, this lower efficacy was seen mainly in patients with CD4 nadir levels below 200 cells/μL. There was no development of PI resistance.”

The National HIV Curriculum is an AIDS Education and Training Center (AETC) Program resource funded by the United States Health Resources and Services Administration. The project is led by the University of Washington and the AETC National Coordinating Resource Center.

The content in this slide set does not represent the official views of the U.S. Department of Health and Human Services, Health Resources & Services Administration.