Rosuvastatin versus Protease Inhibitor Switching for Hypercholesterolaemia in HIV-infected Adults.

ACTRN12612000732886

Status	RECRUITING
Phase	Phase 4
Sponsor	St. Vincent's Hospital, Sydney
Enrollment	60 participants

Plain Language Summary

This study compares two approaches for lowering high cholesterol in HIV-positive adults who are on certain antiretroviral medications. High cholesterol is a common side effect of some HIV drugs. The study compares adding a cholesterol-lowering drug (rosuvastatin) versus switching the HIV drug that is causing the problem, to see which approach works better over 12 weeks.

You may be eligible if:
- You are 18 or older and HIV-positive
- You have been on stable HIV treatment including a ritonavir-boosted protease inhibitor for at least 6 months
- Your HIV is well controlled (undetectable viral load for at least 3 months)
- Your total cholesterol is above 5.5 mmol/L
- You have a meaningful cardiovascular risk (Framingham score 8% or above, or diabetes, or family history of early heart disease)

You may NOT be eligible if:
- You have taken a statin medication in the last 12 weeks
- You have previously had muscle damage from a statin
- You have an existing diagnosis of heart disease or stroke
- You are pregnant or may become pregnant
- You have significant liver or kidney problems

Talk to your doctor about whether this trial might be right for you.

Key Eligibility Criteria

Inclusion (7)

- HIV-positive status
- Adults (>=18 years of age)
- Stable and well-tolerated combination ART including a ritonavir-boosted PI for the previous 6 months
- HIV RNA <50 copies/mL for at least the preceding 3 months
- Fasting total cholesterol >5.5 mmol/L (>213 mg/dL)

... and 2 more (see full listing online)

Exclusion (17)

- Any statin in the previous 12 weeks
- Previous statin-induced myopathy or hepatitis
- History of coronary artery disease, stroke or any other indication for the use of statin therapy (hyperlipidaemia: genetic, secondary or idiopathic)
- Concurrent use of:

• a). oral corticosteroids use other than for replacement therapy (ie. prednisolone 5-7.5 mg, hydrocortisone 20-30 mg, cortisone acetate 25-37.5 mg daily)

... and 12 more (see full listing online)

Locations (1 total)

Australia