

Title

A phase 3, randomized, open label, study of Lopinavir/RTV tablets versus soft gel capsules and once daily versus twice daily administration, when co-administered with NRTI's in antiretroviral naïve HIV-1 infected subjects

Status

Currently enrolling Naïve Trial

Primary Investigator at TGH

Dr. Sharon Walmsley

Sponsor

Abbott Laboratories

Brief Description of the Study

To compare safety and tolerability of the new formulation tablet (LPV/r200/50mg) to the marketed soft gel capsule of lopinavir/ritonavir (LPV/r133.3/33.3mg). Also to compare the daily and twice daily dosing over 48 weeks.

Study Randomizations

1. LPV/r800/200mg **tablet daily**+3TC+tenofovir
2. LPV/r800/200mg **SGC daily** +3TC+tenofovir (then **switch** at week 8 to arm 1)
3. LPV/r400/100mg **tablet twice daily** +3TC+tenofovir
4. LPV/r400/100mg SGC twice daily +3TC+tenofovir (then **switch** at week 8 to arm 3)

Inclusion Criteria

- Naïve with an HIV viral load > 1000 copies/ml
- No CD4 restriction
- Non-pregnant, not breastfeeding
- Active AIDS defining opportunistic infection within 45 days of screening

Contact

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