

'Booster' study

From the NAPWA website at <http://www.napwa.org.au/trials/booster-study>

Clinical trials information

'Booster' study

This trial is **no longer enrolling**. This may mean the trial is fully enrolled, or that enrolment in the trial has been halted or suspended. You cannot enrol in this trial.

About this trial

This study is looking at the safety and [effectiveness](#) (Of a drug or treatment). The maximum ability of a drug or treatment to produce a result regardless of dosage. A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed. In the standard procedure, Phase II clinical trials gauge efficacy, and Phase III trials confirm it. of a new boosting agent or "pharmacoenhancer" called GS-9350 (or Cobicistat).

The drug is used to boost other medications in the blood to make them more effective. Currently, a small dose of ritonavir is often prescribed to perform this function.

All people in the trial will receive a background regimen containing atazanavir + emtricitabine/tenofovir (Truvada) and either GS-9350 or ritonavir as the boosting agent.

Official title:

Phase 3, Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of GS-9350-boosted Atazanavir Versus Ritonavir-boosted Atazanavir Each Administered With Emtricitabine/Tenofovir Disoproxil Fumarate in HIV-1 Infected, Antiretroviral Treatment-Naïve Adults

What is this trial studying?

new_drug – cobicistat (GS-9350)

Start date:

late 2010 (This may be the proposed or expected start date for trials which have not yet started.)

How many participants will this trial enrol?

700 (The exact number of participants may be lower or slightly higher than this. Some trials also have specific quotas for participants from each state, city or clinic.)

How long is this trial planned to go for?

Participants in this trial will be asked to take the trial drug for 48 weeks. Following the conclusion of the trial, participants will be followed up for a further 48 weeks.

Links to further information:

- <http://clinicaltrials.gov/ct2/show/NCT01108510>
- http://www.gilead.com/pr_1635996

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Related trials:

- (<http://napwa.org.au/node/>)

Who can enrol in this trial?

You *may* be eligible to participate in this trial if you meet the following criteria:

- At least 18 years old
- Have never taken HIV treatments
- Viral load at least 5000 copies/ml

This is a summary of key inclusion and exclusion criteria for this trial. There may be other criteria which may exclude some people from participation in this trial. Some laboratory tests may also be required. Consult your doctor, or view the trial protocol or informed consent documentation to see the full range of exclusion and inclusion criteria.

Results:

This Phase 3 clinical trial met its 48-week primary objective of non-inferiority to ritonavir. See link to company press release.

Disclaimer

While NAPWA has taken every care to compile the information on this page and to keep it up-to-date, we cannot guarantee its correctness and completeness.

Before making the decision to participate in any clinical research, visit the NAPWA website for background information on participating in clinical research.

Contact NAPWA if you have any questions or comments about this trial.