

Clinical trials information

Bevirimat monotherapy

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

The main purpose of this research study is to evaluate how effective two different doses of bevirimat are at reducing the amount of HIV in the blood and what, if any, side effects there may be through 14 days of dosing.

This study will also evaluate the [antiretroviral](#) medication or other substance which is active against retroviruses such as HIV. activity and safety of bevirimat in participants who continue with the drug as part of a combination regimen for up to 24 weeks. They also want to know how much of the drug gets into the blood stream following oral administration.

Participants in this trial will be asked to take the trial drug as monotherapy for 14 days and as part of an optimised background regimen for up to 72 weeks.

Background information

Bevirimat, also known as MPC-4326, is a first-in-its-class maturation inhibitor.

Official title:

A Phase II multicenter, open-label, randomized, parallel group, study of bevirimat (MPC-4326) in HIV-1 positive patients to evaluate the safety, efficacy, and pharmacokinetics of bevirimat administered as monotherapy for 14 days and as part of an optimized background regimen for up to 72 weeks.

What is this trial studying?

new_drug –

Start date:

18 April 2008 (This may be the proposed or expected start date for trials which have not yet started.)

How many participants will this trial enrol?

32 (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.)

Links to further information:

- http://www.anzctr.org.au/trial_view.aspx?ID=82830
- http://www.aidsinfo.nih.gov/DrugsNew/DrugDetailT.aspx?int_id=414

Who can enrol in this trial?

Bevirimat monotherapy

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

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
- CD4 count at least 100 cells/mm³
- Viral load between 2000 and 500000 copies/ml
- Treatment-experienced patients must have documented evidence of genotypic resistance in their medical records (at screening) or have a resistance-associated primary mutation at screening by genotype to at least one approved antiretroviral drug. They must also be on a regimen containing at least 3 drugs which has been unchanged for at least 8 weeks prior to initial screening. Note: A washout period of at least 3 days prior to Day 1 of dosing is required.

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 trial is planned to close on December 18 2009.

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.