Clinical trials information

PINT (including raltegravir)

This trial is **fully enrolled**. This means that all of the available places on the trial have been filled. You cannot enrol in this trial.

About this trial

The purpose of this study is to measure how well HIV is controlled in the blood of patients taking a regimen including raltegravir - a drug from the new class of integrase inhibitors.

The trial will enrol eight people who have recently contracted HIV (HIV positive for six months or less) and eight who have had it for a while (positive for more than 12 months). Everyone will be put on raltegravir plus tenofovir and emtricitabine (*Truvada*) and will be followed for a year to see how this new combination reduces virusA small infective organism which is incapable of reproducing outside a host cell. in various compartments of the body and immune system.

Bloods will be taken twice a week for the first four weeks, then at two weekly intervals until Week 12, then at four weekly intervals until Week 24, then at eight weekly intervals until Week 40, with a final visit at Week 52.

Background information

Integrase inhibitors prevent HIV from integrating with immune system cells.

Official title:

The Effect of Raltegravir on HIV Decay During Primary and Chronic Infection (PINT)

What is this trial studying?

new_drug – raltegravir

Start date:

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

How many participants will this trial enrol?

16 (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 12 months.

Links to further information:

- http://clinicaltrials.gov/ct2/show/NCT00641641?term=St+Vincents+AND+HIV&cntry1=PA%3AAU&rank=6

Related trials:

Information on the NAPWA website is provided subject to conditions of use that can be view at napwa.org.au. Visit the website for updated versions of this information.

- (http://napwa.org.au/node/)
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Can I access this treatment other than by enrolling in this trial?

Raltegravir is listed on PBS from 1 July 2008

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
- CD4 count at least 100 cells/mm^3
- Viral load at least 10000 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:

In Phase-2 studies. raltegravir has been shown to have an impressive effect against HIV - with over 70 percent of participants having undetectable viral loads after taking the drug for six months. Particularly encouraging has been the news of how well this drug appears to be tolerated. There have been no serious adverse side effects attributed to this drug in studies so far, and the common side effects of many HIV drugs, such as nausea, headache and diarrhoea, occurred in only very low numbers of people.

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.

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