

Clinical trials information

TMC114 (darunavir)

This trial is **concluded**. This means the trial has been completed. When the results of the trial have been made public, they will be summarised in the 'outcomes' section of this page. You cannot enrol in this trial.

About this trial

This study is testing whether taking 800mg of darunavir once-a-day is as effective as taking 600mg of darunavir twice-a-day. (Both doses will be boosted with 100mg of ritonavir).

Participants will also take an individually selected optimised background regimen. This trial is looking for people who are currently on treatments.

Official title:

A Randomized, Open-Label Trial to Compare the Efficacy, Safety and Tolerability of DRV/Rtv (800mg/100mg) q.d Versus DRV/Rtv (600mg/100mg) b.i.d in Early Treatment-Experienced HIV-1 Infected Subjects.

What is this trial studying?

tx_strategy – ritonavir, darunavir

Start date:

September 2007 (This may be the proposed or expected start date for trials which have not yet started.)

How many participants will this trial enrol?

612 (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 follow the treatment strategy for 48 weeks. Following the conclusion of the trial, participants will be followed up for a further 4 weeks.

Links to further information:

- http://clinicaltrials.gov/ct2/show/NCT00524368?term=HIV+AND+Holdsworth+House&rank=14&show_locs=Y#locn
- http://www.ashm.org.au/uploads/prezistadearhcplletteraus_final.pdf

Can I access this treatment other than by enrolling in this trial?

Darunavir and ritonavir are both available in Australia through the PBS.

Who can enrol in this trial?

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

TMC114 (darunavir)

From the NAPWA website at <http://www.napwa.org.au/trials/tmc114-darunavir>

At least 18 years old
Currently taking HIV treatments
Viral load at least 1000 copies/ml
Need to have been on a stable antiretroviral regimen for at least 3 months

You *will not* be eligible to participate in this trial if you meet any of the following criteria:

- Previous or current use of enfuvirtide, tipranavir and/or darunavir

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.

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.