

BLQ study (darunavir plus enfuvirtide)

From the NAPWA website at <http://www.napwa.org.au/trials/blq-study-darunavir-plus-enfuvirtide>

Clinical trials information

BLQ study (darunavir plus enfuvirtide)

This trial is **concluded**. This means the trial has been completed. The results of the trial are summarised in the 'results' section of this page. You cannot enrol in this trial.

About this trial

This study looked at the new protease inhibitor ([PI](#) type of anti-HIV drug that works by preventing the production of an enzyme, protease, that HIV needs to replicate.) darunavir and how safe, effective and easy-to-take it is with an 'optimised background regimen' including enfuvirtide (T-20).

The trial enrolled people who had been on triple-class therapy before but had never had enfuvirtide or darunavir.

Official title:

An Open-Label Study to Evaluate the Effect on Viral Load of a New Investigational Protease Inhibitor With Fuzeon Plus a Background Antiretroviral Regimen in Triple-Class Treatment-Experienced Patients With HIV-1 Infection

What is this trial studying?

existing_drug – darunavir, enfuvirtide (T-20)

How many participants will this trial enrol?

141 (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 drugs for 24 weeks.

Links to further information:

- http://clinicaltrials.gov/ct2/show/NCT00326963?term=Roche+AND+HIV&cntry1=PA%3AAU&rank=2&show_lo cs=Y#locn
- http://www.hivandhepatitis.com/2007icr/ias/docs/080707_b.html

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

Darunavir and enfuvirtide are both available in Australia through the Pharmaceutical Benefits Scheme (PBS)

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 taken HIV treatments in the past

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

- Taken enfuvirtide before

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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:

The investigators concluded: "In this sample [Expanded Access Program] population of treatment-experienced patients, virologic responses at week 24 were uniformly excellent when darunavir/ritonavir and enfuvirtide were combined with optimized background therapy in patients naive to these 2 drugs."

See link above for full summary

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.