

## Clinical trials information

### NGX-4010 (neuropathy treatment)

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 trial will evaluate whether an [experimental](#) (Of a drug) Not licensed for use in humans, or as a treatment for a particular condition. Experimental drugs are studied in clinical trials to determine their safety and efficacy, and are sometimes made available via Special Access Schemes prior to their approval. drug (NGX-4010) is both safe to use and an effective treatment for the pain resulting from HIV-associated neuropathy.

The study drug contains capsaicin - a substance found in chilli peppers - and is applied to the skin as a patch.

This is a [randomised](#) A method based on chance by which study participants are assigned to a treatment group. Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms. The researchers do not know which treatment is better. From what is known at the time, any one of the treatments chosen could be of benefit to the participant study where people receive either a low concentration patch (acting as [placebo](#) A dummy medical treatment, designed to have no pharmacological effect, administered to the control group of a clinical trial.) or a high concentration patch for a period of 30 or 60 minutes.

#### Official title:

A Multicentre randomized, double-blind, controlled study of NGX-4010 for the treatment of painful HIV-Associated Neuropathy

#### What is this trial studying?

se\_management – NGX-4010

#### Start date:

April 2006 (This may be the proposed or expected start date for trials which have not yet started.)

#### How many participants will this trial enrol?

480 (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 trial protocol for 14 weeks.

#### Links to further information:

- <http://clinicaltrials.gov/ct2/show/NCT00321672?term=NGX-4010&rank=6>

## NGX-4010 (neuropathy treatment)

From the NAPWA website at <http://www.napwa.org.au/trials/ngx-4010-neuropathy-treatment>

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

This is an experimental treatment and not available outside clinical trials.

### 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
- A series of criteria relating to painful HIV-associated neuropathy will be used to determine your eligibility for this study.

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

- Current or recent use of certain drugs which may interfere with the results

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:

Conclusions: A single NGX-4010 application was safe and provided at least 12 weeks of pain reduction in patients with HIV-associated distal sensory polyneuropathy. These results suggest that NGX-4010 could provide a promising new treatment for painful HIV neuropathy. More:

<http://www.neurology.org/cgi/content/abstract/70/24/2305>

### 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.