

## Clinical trials information

### Flupirtine for HIV sensory neuropathy

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 is a one-year extension study to investigate the long-term safety, tolerability and [efficacy](#) (Of a drug or treatment). The maximum ability of a drug or treatment to produce a result regardless of dosage. A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed. In the standard procedure, Phase II clinical trials gauge efficacy, and Phase III trials confirm it. of [open label](#) A clinical trial in which doctors and participants know which drug or vaccine is being administered. flupirtine for the treatment of painful HIV Sensory Neuropathy (HIV-SN) in patients who have pain inadequately controlled by opioids.

#### Background information

Painful HIV-SN is a neurological complication of HIV infection that can result from either the HIV disease process itself and/or from the use of some of the anti-retroviral medications that are used to treat HIV. There has been considerable research into the treatment of painful HIV-SN neuropathy. However, treatment with currently available pain killing medications rarely renders the patient pain free and the use of medications may be limited by side effects.

This current research project is only being offered to the participants who have taken part in the previous research project entitled "A placebo controlled multiple dose research project of Flupirtine for the treatment of painful HIV-SN". Study subjects who did not complete CNSBio 01/7 may be enrolled in this study with the approval of the Principle Investigator and the Sponsor.

The previous study has the protocol number CNSBio 01/07. "CNSBio 01/07" is investigating the short-term (one week) effectiveness and safety of the pain killing medication Flupirtine when taken in combination with opioids for the treatment of painful HIV-SN. CNSBio 01/07 is not yet completed and the results of this clinical trial are not yet available.

The purpose of this research project is to investigate further if the drug Flupirtine is a safe and effective treatment for HIV-SN when taken in combination with opioids for longer than a week (up to one year).

Flupirtine is an experimental treatment. This means that currently the drug is not an approved treatment for painful HIV-SN in the United States by the Food and Drug Administration (FDA) or in Australia by the Therapeutic Goods Administration (TGA). It is however approved for the treatment of back pain, muscle stiffness and pain associated with surgery and arthritis in Germany, Russia, Portugal, China and Brazil. CNSBio Pty Ltd is sponsoring the current research project with the aim of developing Flupirtine for the treatment of painful HIV-SN in Australia and America if flupirtine proves to be safe and effective in this context.

#### Official title:

A one-year, open label, extension study of flupirtine for the treatment of painful HIV-sensory neuropathy in patients who have pain inadequately controlled by opioids

#### What is this trial studying?

## Flupirtine for HIV sensory neuropathy

From the NAPWA website at <http://www.napwa.org.au/trials/flupirtine-for-hiv-sensory-neuropathy>

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### Start date:

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

### How many participants will this trial enrol?

12 (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 1 years.

### Links to further information:

- [http://www.anzctr.org.au/trial\\_view.aspx?ID=82893](http://www.anzctr.org.au/trial_view.aspx?ID=82893)

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

Flupirtine is an experimental treatment. This means that currently the drug is not an approved treatment for painful HIV-SN in the United States by the Food and Drug Administration (FDA) or in Australia by the Therapeutic Goods Administration (TGA). It is however approved for the treatment of back pain, muscle stiffness and pain associated with surgery and arthritis in Germany, Russia, Portugal, China and Brazil. CNSBio Pty Ltd is sponsoring the current research project with the aim of developing Flupirtine for the treatment of painful HIV-SN in Australia and America if flupirtine proves to be safe and effective in this context.

### 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
- Participants must have completed the primary study identified by the protocol number CNSBio 01/07 . Study subjects who did not complete CNSBio 01/7 may be enrolled in this study with the approval of the Principle Investigator and the Sponsor.

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.