# FDA: further trial needed for Huntexil approval in HD

**Bad news for Huntexil – the FDA requires another trial before it can be approved in the US**

A new article has been published with updated information on this subject:No surprises in published results from HART study of Huntexil for Huntington's disease

By Dr Jeff Carroll | April 04, 2011 | Edited by Professor Ed Wild

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NeuroSearch, the developer of experimental Huntington's disease drug Huntexil, has reported on their meeting with the FDA. The FDA requires that another trial be conducted before Huntexil could be approved in the US.

## What is Huntexil?

As previously discussed on HDBuzz, Huntexil is an experimental drug, specifically developed to help with some of the movement problems associated with Huntington's disease. Also known as pridopidine and ACR16, Huntexil is made by a Danish company, NeuroSearch.

What trials have been done with Huntexil?

NeuroSearch sponsored two trials of Huntexil in HD patients. The first involved 437 patients in the European Huntington Disease network, called the 'MermaiHD' trial. The second, with the Huntington Study Group in North America, was called the 'HART' study and included 227 patients.

The MermaiHD trial was frustratingly inconclusive. While some improvement was seen in patients' movement symptoms, the findings weren't robust enough to call the trial a definite success. Something very similar happened with the HART study - improvements in movement symptoms were seen, but they weren't strong enough to be conclusive.

NeuroSearch pooled the results of the MermaiHD and HART trials together, in what is known as a 'meta-analysis'. This allows scientists look at the results from multiple studies together. That analysis **did** show a robust improvement in the movement symptoms in HD patients. But it wasn't clear whether that would be enough to get the drug approved.

In general, the regulatory agencies that approve drugs for patient use don't allow this kind of 'meta-analysis' to be used as evidence for a drug being effective. Usually, the results of a single, planned trial are presented and considered as evidence. Still, NeuroSearch said that they would present the results of their meta-analysis to the FDA, and argue that it was sufficient proof that Huntexil worked.

# What's just happened?

On March 23rd, NeuroSearch announced that they'd had a meeting with the FDA called an "end of phase II meeting". At this meeting, the FDA told NeuroSearch that they would need "additional clinical evidence" to apply for approval for Huntexil in the USA. That means that the FDA would require the results of a further clinical trial before Huntexil could be approved.

# Now what?

NeuroSearch has also applied for approval for Huntexil from the European Medicines Agency (EMA). They expect to hear from the EMA sometime by June 2011 whether the meta-analysis they conducted will be enough to get Huntexil approved for use in Europe.

As for the USA, NeuroSearch will have to run another trial to get approval for Huntexil. CEO, Patrik Dahlen, said in a press release that their plan for new trials "is currently being developed". Their decision will likely be influenced by whether Huntexil is approved in Europe or not.

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*The authors have no conflicts of interest to declare.For more information about our disclosure policy see our FAQ...*

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**GLOSSARY**

**clinical trial** Very carefully planned experiments designed to answer specific questions about how a drug affects human beings

**meta-analysis** Combining the results of several different studies and analyzing them together, to increase their ability to answer a particular question.

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