Nycomed begins clinical testing of gaseous MRI contrast agent

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A new kind of MR contrast medium, hyperpolarized gas, has moved from the laboratory into clinical trials. Researchers at three medical centers in the U.S. have begun evaluating a gaseous isotope, helium 3, for use as an MRI contrast agent. When excited with laser light, this type of helium generates a unique MRI signal. Inhaled hyperpolarized helium 3 helps generate a view of the lungs that could not otherwise be seen with MRI.

Until now, academic research on hyperpolarized gases had not explored their potential clinical value. Clinical tests represent a milestone in the development of hyperpolarized gas technology—the first effort aimed at winning FDA approval for widespread commercial use.

I can show you a fascinating picture of lung structure (taken with hyperpolarized helium), but it does not demonstrate any particular clinical use, said John Padfield, CEO of Nycomed Amersham Imaging. What we have to do is demonstrate diagnostic utility—the benefit that it will give clinicians and patients.

Nycomed Amersham Imaging hopes to usher this technology called HeliSpin through the FDA, having last year bought the only company focused on its development, Magnetic Imaging Technologies (MITI) of Durham, NC. The phase I trial is designed to document the safety of using HeliSpin for lung imaging. Later tests may determine the diagnostic value of the product in patients with asthma, cystic fibrosis, and chronic obstructive lung diseases such as emphysema, as well as those undergoing lung surgery or transplantation.

Of Nycomed’s hyperpolarized gases, HeliSpin is the furthest along in development, but it is not the only one. Soon to enter preclinical testing is xenon-129, dubbed XenoSpin. Because this agent dissolves rapidly into the blood, qualitative—or even quantitative—assessment of blood flow through the circulatory system, as well as organ perfusion, might be possible. XenoSpin may also be useful in lung studies.

With the acquisition of MITI in August, Nycomed Amersham now holds virtually exclusive commercial ownership of the technology. The licenses MITI had obtained regarding hyperpolarized gases from Princeton University and the State University of New York at Stony Brook are now in the hands of Nycomed Amersham.

Over the last year, and through its preceding partnership with MITI, Nycomed has fine-tuned gas technology as a contrast agent and developed the equipment needed to create hyperpolarized gases.

Making and using these isotopes can be tricky. Like radiopharmaceuticals, hyperpolarized gases decay over time, into nonpolarized gas. Nycomed is working on ways to slow the decay, utilizing plastic containers that have little interaction with the gas. The company is also developing technology that could be used to reenergize the gases as they drop to a depolarized state.

Nycomed plans to use its global organization to market and sell hyperpolarized contrast products. The details of distribution and sales have not yet been worked out. One possibility is to develop and sell a generator that can create hyperpolarized gases at the MRI site. In such a case, Nycomed would sell both the generator and the raw materials.

We would not sell the technology so other people could produce the polarized gas, Padfield said.

We see the two as integral parts of the whole—a bit like selling software and computers together. Before commercialization can happen, however, hyperpolarized gases must clear the FDA. Academic studies were assisted during the mid to late 1990s by an FDA policy that considered these gases devices posing no significant risk to humans. The agency has since reclassified them as drugs. As a result, they require the same lengthy and detailed study as other pharmaceuticals.

The phase I clinical trials to document safety should be simple, as helium is a noble gas and, by definition, does not interact with other compounds. Combined phase II and phase III trials, scheduled to begin early next year, will determine whether HeliSpin has a place in the practice of medicine and,
consequently, on Nycomed Amersham Imaging’s bottom line.

**Disclosures:**

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