



November 2003 Taking Research From Bench to Bedside: Part II of II

Inside this issue...

Clinical Trials at UHN (Part II)

Finding the Best Treatment for Heart Failure

Patients Use Aids to Understand Cancer

Treating Psychotic Depression

Attacking the Cause of Lung Disease

Testing a New Rapid Treatment for Prostate Cancer

Imaging Parkinson's Disease


Novel Therapy for Ankylosing Spondylitis

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In the first part of this two-part special, we described five clinical trials at UHN. Below we describe more of the many clinical trials which have taken place, are taking place, or will soon take place at UHN.

New Heart Failure Study Compares Medical and Surgical Treatments

UHN is the lead recruiting centre of a new NIH-funded study of 2800 patients that will determine the best treatment options for patients with heart failure.

TGRI/TGH's Dr. [Vivek Rao](#) is the leader of the UHN arm of the Surgical Treatments for Ischemic Heart Failure, or STICH, trial. The trial involves more than 90 centres in 15 countries, and will study the outcomes of three treatment regimens: medication alone, medication with coronary artery bypass surgery, or medication with coronary artery bypass surgery and surgical reconstruction of the heart ventricle. 

Surgical reconstruction is often needed because the ventricle becomes enlarged and weakened over time, as it struggles to pump blood.

"There is currently very little information about how doctors should treat patients with heart failure," explains Dr. Rao. "Hopefully this study will provide us with some definite answers."


Doctors identify about 550,000 new heart failure patients each year, and it is the leading cause of hospitalization in North Americans over the age of 65.

For more information about this study, visit www.stichtrial.org.

Institute: TGRI/TGH
Division: Experimental Therapeutics
Priority Platform: Medical Technology Innovation

Decision Aids Ease Uncertainty About Cancer

Access to help in decision-making may improve the quality of decisions people with incurable cancer make, says Dr. [Natasha Leighl](#), an OCI/PMH oncologist conducting the world's first randomized study evaluating the use of decision aids (DAs) in 200 advanced cancer patients.


Dr. Leighl developed the DAs to help patients better understand their illness and choose the treatments that are best for them. The DAs consist of an information booklet and audiotape or CD, that patients can peruse at their leisure. 

"The DAs review the treatment options available to patients, both in terms of how well they work and the types of side effects patients can expect," explains Dr. Leighl. "A better understanding is key for patients to become more involved in making decisions about their own treatment, and we hope that patients will be more satisfied with the cancer care they receive."

The clinical trial testing the use of the DAs is underway at OCI/PMH and the University of Sydney, Australia.

Institute: OCI/PMH
Division: Clinical Studies Resource Centre

Groundbreaking Study Offers Hope for Patients With Psychotic Depression

A combination of medications is being tested at UHN as a treatment for psychotic depression, a particularly severe form that is seen in up to 25% of hospitalized depressed patients. 

The study, funded by the National Institutes of Mental Health (NIMH), is being conducted by Dr. [Alastair Flint](#) (TGRI/TGH) and colleagues in Toronto, together with researchers at three US centres.


It compares the effect of a combination of antidepressant and antipsychotic medications with antipsychotic medication alone. Additional goals of the study are to evaluate the effect of aging and cerebrovascular risk factors on rates of response and patients' ability to tolerate treatment.

It has been more than 20 years since the NIMH funded a study of the pharmacologic treatment of psychotic depression. This trial breaks new ground in that it evaluates state-of-the-art medications. The study is expected to involve 315 patients.

Institute: TGRI/TGH
Division: Behavioural Sciences & Health

New Trial Uses Drugs to Attack Molecular Target in Severe Lung Disease

TGRI/TGH's Dr. [Charlie Chan](#), head of the Division of Respiriology at UHN, is currently conducting a clinical trial of a new treatment for a serious lung disease.


Pulmonary fibrosis (PF) is a disease that causes the lungs to stiffen, interfering with a person's ability to breathe. In many cases it is idiopathic, meaning there is no known cause. "Idiopathic PF has a very poor prognosis for a chronic disease," says Dr. Chan. "Its mean survival is 2-4 years and there are no effective treatments." 

The study focuses on endothelin-1, a peptide that is expressed in abnormally high levels in the lungs of patients with the disease. It causes blood vessels to constrict, and researchers believe it may be possible to slow the progression of the disease if drugs are used to prevent its actions.

Dr. Chan is currently testing this hypothesis in collaboration with 27 other centres in Canada, the US, Europe and Israel. It is expected that a total of 200 patients will participate.

Institute: TGRI/TGH
Division: Clinical Investigation & Human Physiology

Pioneering Prostate Cancer Treatment Promises Speed

One of the world's first trials of a new method of delivering radiation to treat prostate cancer—called hypofractionated intensity modulated radiation therapy (IMRT)—is currently being tested on 200 patients at OCI/PMH. 

"Prostate cancer has features that make it different from most other forms of cancer, and it responds differently to radiation therapy," explains Dr. Charles Catton, leader of the study. "We believe we can take advantage of this unusual characteristic to deliver larger daily doses of radiation over a shorter period of time, rather than smaller doses over a longer period of time."

If the treatment proves effective, the overall treatment times for prostate cancer could be cut in half, doubling the capacity of hospitals to treat patients and improving patient convenience.

Institute: OCI/PMH
Division: Clinical Studies Resource Centre

Featured below are two clinical trials recently wrapped up at UHN.

Researchers Image Parkinson's Disease Progress in First-Ever Study

Dr. [Anthony Lang](#) (TWRI/TWH), in collaboration with researchers at nine other centres around the world, recently conducted a clinical trial that for the first time used an imaging technology (positron emission tomography, or PET) to assess Parkinson's disease (PD) progression in 186 patients with the disease.

Patients newly-diagnosed with the disease were treated with either L-dopa, the standard treatment for PD, or with a new drug called ropinirole. The researchers used PET to visualize the brain over the two-year study and were able to map the damage to the neurons involved in PD.

Patients treated with ropinirole had less damage to these neurons than did the patients treated with L-dopa, suggesting that ropinirole may slow the progression of PD.

Ann Neurology. 2003, 54(1):93-101
[\[PubMed abstract\]](#)

Institute: TWRI/TWH
Division: Applied & Interventional Research

New Treatment Offers Relief to AS Patients

A recent report from TWRI/TWH rheumatologist and Director of the Arthritis Centre of Excellence Dr. [Robert Inman](#) has shown that a genetically engineered drug called etanercept is effective in treating ankylosing spondylitis (AS).

AS is a type of arthritis that primarily affects the spine. It is caused when the joints and muscles of the back become inflamed, resulting in pain, stiffness and eventually immobility.

"The cause of AS is mysterious," says Dr. Inman, "but patients with the disease have unusually high levels of an inflammation causing protein called TNF. Etanercept works to block the effects of TNF by binding to it."

The study showed that after six months, patients treated with the drug had less pain and were able to function better than patients who did not receive the drug. The study was conducted in collaboration with researchers at 27 other centres in five countries.

Arthritis & Rheumatism. 2003, Vol 48(11):3230-3236
[\[PubMed abstract\]](#)

Institute: TWRI/TWH
Division: Cell & Molecular Biology

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