

Clinical Trials in the Northwest are improving the lives of cancer patients

BY KIM LATIMER

CLINICAL Trials at Regional Cancer Care (RCC) and the Thunder Bay Regional Health Sciences Centre (TBRHSC) are impacting, improving and prolonging people's lives. More patients than ever before are contributing to the discovery of national and international medical research.

Cancer Clinical Trials have been conducted for 25 years at Regional Cancer Care and the Thunder Bay Regional Health Sciences Centre. Many of the clinical trial studies are international in scope and have resulted in major breakthroughs in the management of cancer.

Dr. Adrien Chan, Medical Oncologist at Regional Cancer Care, has been instrumental in the success of the clinical trials program. He says the program raises the bar because it offers the very best leading-edge care to patients.

"Clinical trials research is a cornerstone of oncology. Participation in clinical trials allows patients to receive treatments that may be more effective than the standard treatments." Dr. Chan adds, "the knowledge gained through clinical trials advances cancer treatment."

Cindy Sinnott has been a clinical trials research nurse and research coordinator for 18 years. She says prevention studies are also advancing patient care.

"Studies conducted at RCC have included prevention of breast, prostate, colon and lung cancers using anti-hormonal, antioxidants, anti-inflammatory, statins and other agents," Sinnott

says.

"For participants and the general population prevention studies offer hope in trying to prevent their risks of developing the disease."

Examples of some of the multi-centered international studies:

Breast Cancer Primary Prevention Study

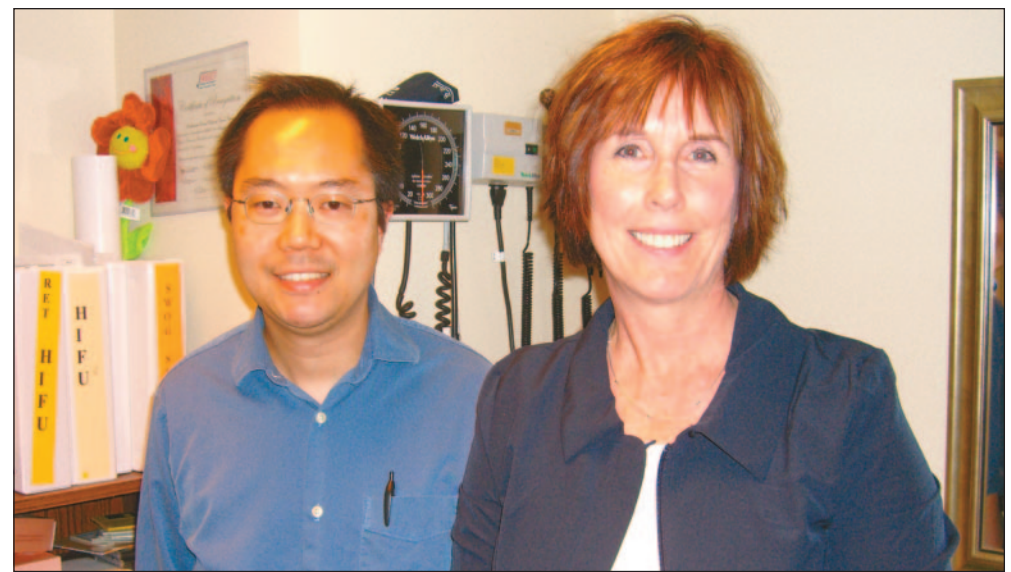
The first and largest national breast cancer prevention study ever conducted in the world. Results proved that the drug Tamoxifen prevented invasive breast cancer by 50%. This was a major scientific breakthrough in breast cancer prevention and the area of prevention studies. The study included 48 RCC participants. One of the participants was selected to sit on a national participant advisory board.

STAR Primary Breast Cancer Study

The study of Tamoxifen and Raloxifene for the prevention of breast cancer shows that the drug Raloxifene (initially used to prevent and treat osteoporosis) improved its effectiveness against noninvasive breast cancer. After 81 months of follow-up, although Raloxifene was slightly less effective against invasive breast cancer, it still maintained strong efficacy. The clinical trials team at RCC is continuing to follow 75 female participants.

Prostate Cancer Primary Prevention Study

The study of Finasteride in the Prevention of Prostate Cancer showed that the drug Finasteride



Medical Oncologist Dr. Adrien Chan says clinical trials are advancing cancer treatment. He's pictured here with clinical trials research nurse Cindy Sinnott

(currently used to treat benign prostatic hypertrophy) showed minimal benefit in the prevention of prostate cancer. This study involved 20 participants from Regional Cancer Care.

Colon Cancer Secondary Prevention Study

The local cancer centre is currently seeking participation in a secondary prevention study for the prevention of polyps in patients with resected colon cancer. Colorectal cancer prevention is a clinical imperative, and a key part of prevention involving the search for drugs

that can safely and effectively block or reverse colorectal cancer development.

Select Trial

The Select Antioxidant study used Selenium and Vitamin E in the Prevention of Prostate Cancer. This study showed no benefit in the prevention of prostate cancer. Secondary endpoints also showed no benefit in the prevention of colon, lung cancers and skin cancers and is following participants to learn more about men's health. This study involved 35 local participants.

Breast cancer patients in Northwest participate in national clinical trial

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A group of 29 women at Regional Cancer Care participated in a radiation treatment trial for breast cancer. They were part of a larger group of over 1800 women from across Canada, the United States and Australia who participated in the randomized study led by the National Cancer Institute of Canada Clinical Trials Group.

The study focused on improvements in outcome for women diagnosed with early stage breast cancer following breast conserving surgery and systemic treatment.

The women who participated were selected into two groups to determine whether regional radiation treatment to the axilla and breast lymph nodes plus the breast increased survival compared to radiation treatment to the breast alone. The women who are participating in the trial will be followed for several years before the final results will be available.

Dr. Margaret Anthes is a radiation oncologist at Regional Cancer Care. She is also the principal investigator for this radiation trial for breast cancer. She says the results will be compared and evaluated throughout the patient journey from treatment through to recovery and survival.

"Women will be monitored and evaluated based on a number of criteria including: disease free survival, the effects of toxicity, quality of life, and cosmetic outcomes", says Dr. Anthes.

A number of experienced staff members are involved in the study



Radiation oncologist Dr. Margaret Anthes, radiation therapist Kasey Etrene and certified clinical research associate, Melny Zizman work closely with patients, families and staff as part of the clinical trials team. They're pictured here with one of the radiation therapy machines at Regional Cancer Care.

due to its length and scope. They have many years of combined experience which they bring to this, and other clinical trials happening, at Regional Cancer Care and Thunder Bay Regional

Health Sciences Centre. The clinical trial program itself has supported over 25 years of successful clinical trials.

Kasey Etrene is a radiation therapist who has worked at Regional Cancer Care for 24 years, and has worked in clinical trials for the past 12. She's witnessed cancer care improvements from a frontline, first-hand perspective.

"Over the last 25 years clinical trials have made extraordinary advances in cancer prevention, treatment and survival. I expect to see more in my career and I find the work very gratifying to know that we do make a difference," says Etrene.

Roberta Kavalchuk has been a registered nurse at Regional Cancer Care for 28 years. She has been working area of clinical trials for the past eight and a half years. She says it is her hope that this study will determine the best possible treatment approach and shape best practice.

"Women with breast cancer endure a great deal during their journey," she says. "It is rewarding to know that a trial that I am involved with could influence better treatment for some cancer patients."

Melny Zizman, a certified clinical research associate who has worked in clinical trials for 20 years, says she couldn't agree more. She says the most rewarding part for her is seeing patients in Northwestern Ontario receive improved access to care.

"It is a good feeling to know that clinical trials allow cancer patients in our community the opportunity to have access to the most up to date treatment available."

Lung cancer clinical trial underway

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A lung cancer vaccine is in clinical trial at Regional Cancer Care Northwest. The vaccine was originally designed to increase patient survival by three months. The results of the first trial sponsored by a pharmaceutical company to use this vaccine far surpassed this goal, increasing survival by 17 months.

The study involves 1322 patients from more than 250 centres worldwide. The vaccine is for patients who have been diagnosed with advanced non-small cell lung cancer. Thunder Bay Regional Health Sciences Centre took part in this early study, which started in 2000.

Phase III of the vaccine, meaning it is being compared with the standard treatment to see if it is more effective is now part of a national study and began at Regional Cancer Care in 2006.

Amy Boucher is the study coordinator on this trial. She's been a research nurse and clinical research professional at Regional Cancer Care since 2004.

Boucher says this vaccine could have the potential to improve the quality of life for patients here in the Northwest.

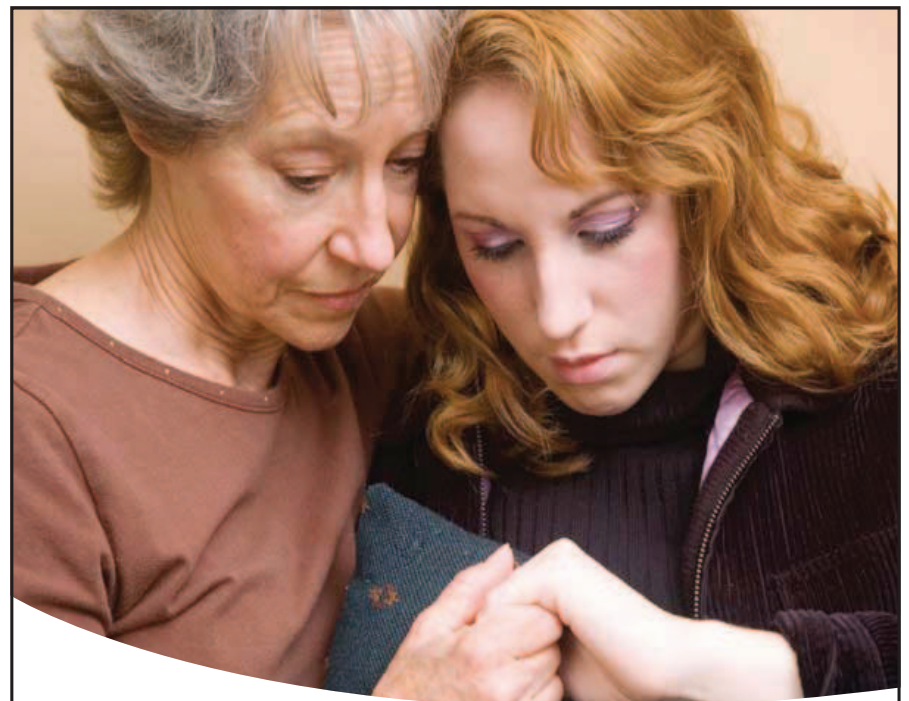
"It is an honour to be part of such novel, exciting research," says Boucher. "There is a lot of hope that this vaccine can offer a new treatment option for patients with advanced non-small cell cancer."

So far the trial has been successful. The patients involved in this trial have done very well, Boucher says. Several patients have survived more than seven years and they continue to receive the vaccination. However, Boucher points out that the final results of the research will not be known until the Phase III trial is complete.

Researchers are optimistic about the preliminary results so far.

"When you work in research you are looking into the future," says Carol Barbosa, Certified Clinical Research Associate working in clinical trials at Regional Cancer Care for 10 years.

"It is rewarding to be part of a study where the results for patients can be seen in the present



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New drug being trialled is the last option for some colon cancer patients

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A drug being tested in a phase III study to treat colon cancer is in the final stages of clinical trial at Regional Cancer Care. Seven patients from the Northwest were some of the first selected to participate when the study began in 2003.

Over 570 patients participated in the Canadian-led study by the National Cancer Institute of Canada Clinical Trials Group. Patients selected for this study had previously failed two chemotherapy regimens to treat their colorectal cancer. This clinical trial is something that Regional Cancer Care could offer them.

Dr. Dorie Anna Dueck is the Medical Oncologist and principal investigator of the study at Regional Cancer Care. This drug has already been successful in Phase I and II studies. Researchers have noted a demonstrated improvement in both survival and the

time until cancer progresses. Oncologists around the world are sitting up and taking notice.

The drug used in this study is an antibody agent. It has the potential to be the first biological targeted therapy for colorectal cancer – meaning for patients that express a certain protein found on the surface of some cancer cells, the drug recognises and attaches to this protein.

Tumors that have this protein may respond to this drug.

"This study is changing practices worldwide for improvements in survival of patients with chemotherapy refractory (resistant) colorectal cancer and it is exciting to know that it was achieved with the contribution of clinical trial patients right here in Northwestern Ontario," says Nancy Donahue, a certified clinical research associate who has been working in clinical trials for 24 years.