

Headlines

Spring 07

A newsletter for brain tumour patients and their families

MEDICAL UPDATE

A Guide to Clinical Trials

CANCER CENTRES OFTEN CONDUCT CLINICAL TRIALS to identify better treatments for patients. Clinical trials are research studies involving humans that aim to answer important questions about health and treatment in carefully designed, scientifically meaningful ways. The decision to participate in such a study is a personal one, and is always voluntary.

Before a clinical trial takes place, extensive "preclinical" research is conducted in laboratories using animal subjects. Sometimes the media publish reports about treatments that appear to be effective in treating diseased rats and mice even before they have ever been tested in people. In fact, this is only the first step in evaluating a new therapy. After preclinical studies identify a promising new treatment, a trial investigator must submit a detailed proposal or protocol for a study of that treatment in humans to Health Canada. The protocol is a plan for the study, and outlines the procedures that will be used to safeguard human participants and to answer specific questions about the treatment under investigation. Government officials review the protocol to ensure the protection and safety of the participants; assess the quality

of drugs; assure review by Research Ethics Boards (REBs); and verify the qualifications of Principal Investigators and monitors. If the trial appears to be well designed and safe, and if it offers the potential of a meaningful advantage to study participants, Health Canada may approve it. After this initial approval, the investigator must present the trial to the local REBs, in both the hospital(s) and sponsoring university(ies) where the trial will take place, for final approval. REBs are composed of health care professionals as well as members of the lay community.

All clinical trials have guidelines about who may participate. These are called inclusion and exclusion criteria and include such details as age, general wellbeing, presence of any other illnesses, and type and stage of disease. By restricting criteria for entry in a clinical trial, all study participants are as similar as possible in many important respects. Sometimes clinical trials compare an experimental treatment to the standard treatment in use for a particular condition. If the patients are very similar in terms of their disease and

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Phases of clinical trials

Phase I: Is it safe? Researchers test an experimental drug or treatment in a small group of people for the first time to determine a safe dosage and identify side effects.

Phase II: Does it work? The experimental drug or treatment is given to a larger group of people to see if it is effective and to collect more information about its safety.

Phase III: Is it better than the treatment we already use? The

experimental drug or treatment is given to very large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and further evaluate safety.

Phase IV: What are the longterm effects of the new treatment?

Additional information about the experimental treatment is collected even after the drug is marketed, including the drug's risks, benefits, and optimal and longterm use.

Nutrition and cancer

PEOPLE OFTEN ASK FOR RECOMMENDATIONS about diet when they are undergoing treatment for a brain tumour, or even if they have finished treatment and want to remain well. Although there has been extensive research on diet and cancer, most of this research has focused on particular foods or nutrients and their impact on tumour formation and growth in a particular site in the body, especially in breast, prostate and gastrointestinal cancers. These findings suggest that a healthy diet may prevent some types of cancer, although there is little information about diet and prevention of brain cancer specifically.

Studies demonstrate that obesity is a significant risk for many types of cancer, including esophagus, colon and rectum, gallbladder, pancreas, stomach, kidney, prostate, breast, uterus, cervix and ovary. Refined sugar (such as in candy bars and soft drinks), unrefined sugar (for example, honey and fruit juice), and refined flour (flour which has had wheat germ and bran removed) may also contribute to health problems, especially the development of diabetes. Diabetes has been linked to heart disease and some kinds of cancer, notably colorectal, endometrial and pancreatic cancer. Some people are concerned that sugar may “feed” tumour cells. Sugar is found in all carbohydrates, including fruits, vegetables, and whole grains. It is an important source of energy for all cells, cancerous and healthy alike. By eliminating sugar entirely from the diet, healthy cells may be harmed. Red meat has been linked to colorectal and breast cancer, and according to some studies, should be eaten in restricted quantities. Foods that are high in cholesterol and saturated fats may promote cancer and heart disease, although foods rich in omega 3 fats (found

in flaxseed oil, fish, and some eggs) offer protection against these diseases.

So what other foods should you eat if you want to avoid cancer? There is overwhelming evidence that a diet rich in fruits and vegetables protects against many kinds of cancer, diabetes and heart disease. Even in lung cancer studies, consumption of fruits and vegetables cuts the risk of lung cancer, even in smokers. There are numerous healthful substances in these food groups, and a wide variety of fruits and vegetables, taken on a daily basis, ensures a varied intake of nutrients. These foods also supply fibre in the diet, and high fibre diets appear to protect against gastrointestinal cancers. In addition, fruits and vegetables are a rich source of antioxidants (vitamin C, E, selenium, and alpha- and beta-carotene), which prevent DNA damage and thus protect against mutations causing cancer. Folate, found in dark green leafy vegetables, also plays a role in DNA integrity and has been proven to prevent brain tumours in children when taken by their pregnant mothers.

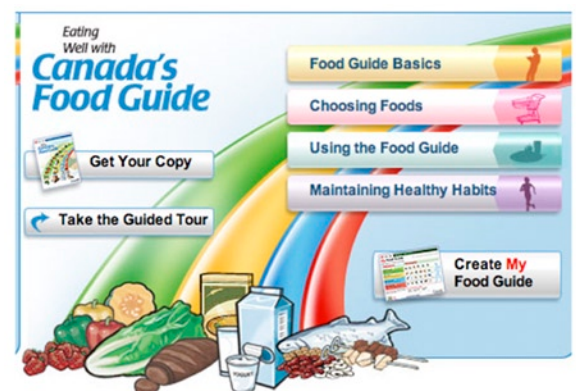
If it seems that some foods may prevent cancer, what if you already have cancer, such as a brain tumour? The research is much less clear about the role diet plays in fighting tumours. In some cases, the substances that may prevent cancer may also interfere with treatments aimed at fighting cancer. For example, antioxidants prevent damage to the DNA of cells, which over time might lead to mutations resulting in cancerous cells. However, chemotherapy and radiation therapy work by damaging the DNA of tumour cells so that these cells are unable to reproduce. It is therefore possible

that antioxidants might fix the damage done to tumour cells by cancer treatments. Ask your doctor for advice about the use of antioxidants throughout your treatment.

When challenged by illness and the harsh treatments used to fight cancer, our bodies have an even greater need for protein to repair and build tissues, vitamins to assist with normal functioning and replenishment of cells, and minerals for healthy bones, teeth and blood. Dietary sources of calcium and vitamin D may need to be supplemented if you are taking dexamethasone or seizure medicines, as these drugs may cause your bones to become weak. There is little evidence that eating nutrients in excessively large doses results in better outcomes for those with cancer.

The bottom line is that your body needs adequate, but not excessive calories for energy, and a healthy diet composed of a variety of nourishing foods, rather than “empty calories” or a restricted range of foods. Canada’s Food Guide offers help in choosing the right kinds of foods in the amounts that lead to optimal health. If you have specific concerns about your nutrition, talk to your doctor or nurse, or make an appointment with the dietician in your cancer clinic.

With thanks to Angie Bowman, Registered Dietician, Oncology Nutrition, BCCA



For more information about cancer and diet, see:

http://www.cancer.org/docroot/PED/content/PED_3_2X_Common_Questions_About_Diet_and_Cancer.asp

<http://www.bccancer.bc.ca/HPI/CancerManagementGuidelines/SupportiveCare/naturalhealthproducts/cancertherapy.htm>

For the Canada Food Guide, see: http://www.hc-sc.gc.ca/fn-an/food-guide-aliment/index_e.html



IT IS TIME AGAIN TO LACE UP YOUR SNEAKERS to join the thousands of people helping to reach Canadians affected by a brain tumour. Register now for the Brain Tumour Foundation of Canada Spring Sprint through the BTFC website (www.braintumour.ca),



or contact Eileen Quigg by telephone at 1.800.265.5106!

All proceeds go toward supporting the Brain Tumour Foundation mission:

to reach every Canadian affected by a brain tumour through support, education and information, and funding brain tumour research. This year the BTFC will be hosting 19 Spring Sprint events throughout Canada. Last year, the Spring Sprint raised a spectacular \$750,000!

In British Columbia, the sprint will be held at:

Greater Vancouver: Saturday, May 5, Riverfront Park, Burnaby, 10 am

Victoria: Sunday, May 6, Cedar Hill Recreation Centre, 9 am



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A Caregiver Education Series

My loved one has a terminal illness How do I cope?

Join with others who are caring for a family member or friend with a life-threatening diagnosis. Getting information, answers and support from professionals in the field will help combat the isolation you feel and give you a chance to network with people in a similar situation.

DATES: Six Saturday mornings: May 5th to June 16th, 2007 (NO class May 19th)

TIME: 10 am – 12:30 pm

LOCATION: Raven Song Community Health Centre ~ Room 101
2450 Ontario Street, Vancouver BC (Ontario & 8th Avenue)

FEE: \$25 *Cost will not be a barrier to anyone. Please contact us for a reduction or waiver.

FOR MORE INFORMATION OR TO REGISTER: Contact: Will Tessier at 604.688.5161 or wiltessier@gmail.com

Do you suffer from Claustrophobia?

Marni Besser, Registered Nurse at the BC Cancer Agency, will attempt to document the number of brain tumour patients experiencing this problem in relation to their treatments and brain scan appointments. If you suffer from claustrophobia, please let your doctor or nurse know so that Marni can be notified. She will contact you with suggestions for managing this problem. She will also share her findings about the prevalence of this problem with cancer agency staff at the end of the six month data collection period.

Editions of *Headlines* are also available as a pdf download at:

www.bccancer.bc.ca/HPI/CancerManagementGuidelines/NeuroOncology/PatientResources.htm

If you would like to submit an article, ask a question, or serve on our patient and family advisory board, please contact Rosemary Cashman at rcashman@bccancer.bc.ca or 604.877.6072 (phone) 604.877.6215 (fax).

All content by Rosemary Cashman unless otherwise specified.

Q I was reading about the gamma knife and wonder why we don't have this in Canada. I have a grade 3 brain tumour and had surgery, radiation and chemo, but my tumour keeps coming back. Should I go to the United States for the gamma knife?

A The Gamma Knife is a radiation therapy machine designed to give a treatment called stereotactic radiosurgery. Stereotactic radiosurgery, or SRS, is precision radiation therapy given in a single treatment session for small tumours within the skull, in such a way that treatment is very tightly focused on the tumour and treats very little normal tissue. Another technology also available to give this treatment is the linear accelerator, or linac, which is used to give conventional radiation therapy but can be specially adapted also to administer SRS. Both the Gamma Knife and the linac are excellent ways to give SRS. In general, there is no particular advantage to one technology over another. In fact, there are now three Gamma Knife facilities in Canada, in Winnipeg, Toronto, and Sherbrooke. In addition, Canada has a

long, proud tradition of linac SRS, with centres in Halifax, Montreal (2), Ottawa, Toronto, Hamilton, Toronto, London, Calgary, and, Vancouver (at the BC Cancer Agency Vancouver Centre).

The most important consideration is whether SRS of any sort is an appropriate treatment for the condition we are facing. SRS is always reserved for relatively small tumours, less than 3.5 cm. Grade 3 astrocytomas and other high-grade gliomas are usually too big for SRS to be a good option. Also, because it is so tightly focused, SRS is best suited for very well-defined tumours. Over many years, our experience has taught us that high-grade gliomas are quite ill-defined with microscopic tumour extending beyond what we can see on an MRI or CT scan. Accordingly, the concern is that SRS will miss tumour much of the time. Another issue is side effects. In your situation, SRS would mean reirradiation of a portion of your brain that has already received

conventional radiation therapy. We know that this can be associated with a relatively high risk of radiation-induced damage, or radionecrosis, which can lead to disability, an increased need for steroids, and even the need for further surgery. Accordingly, even if the recurrent tumour is small, in the management of recurrent high-grade glioma, SRS should be considered in very carefully selected circumstances and with great caution.

In short, there is no need to travel to the United States for Gamma Knife or any other form of SRS. An opinion regarding whether yours may be one of the very uncommon cases of recurrent high-grade glioma in which SRS may be a consideration can be obtained from any radiation oncologist in Canada who specializes in treating brain tumours.

*by Dr. Michael McKenzie,
Radiation Oncologist, BC Cancer Agency*

Question + answer



A Guide to Clinical Trials *continued from page 1*

general condition, it is more likely that any difference in outcome between the experimental and standard treatment is due to the treatment, rather than some other factor. Clinical trials also have strict guidelines about how the study will proceed and how and when assessments of participants will take place. Before a participant agrees to be in a study, he or she must provide written informed consent. Informed consent is an ongoing process through which participants learn key information about a trial, such as the reason for the study, the required study procedures, and the potential risks and benefits of their participation. Some of the benefits of clinical trial participation for a patient may include:

- Ability to take a more active role in decisions about care

- Quick access to new treatments before they are widely available
 - Opportunity to help others by contributing to medical research
- Some of the risks may include:
- Unpleasant or dangerous side effects of experimental treatments
 - Ineffective treatment
 - Extra tests or procedures to assess your safety and the effectiveness of the treatment

It is important to ask questions and be well-informed before deciding to participate in a clinical trial. And it is always your right to withdraw from participation if you choose, without compromising your care.

Clinical trials are conducted in phases. Understanding which phase the study is going through may help you to decide whether you wish to participate.

Some of the other questions you might ask before deciding to participate in a clinical trial include:

- What are potential side effects of the experimental treatment?
- What is the alternative to participation in this trial?
- How will my safety be protected?
- Will I need to come to the hospital/clinic more frequently if I agree to participate?
- Will there be any additional costs to me if I participate?

For more information about clinical trials see: <http://clinicaltrials.gov/ct>
http://www.cancer.ca/ccs/internet/standard/0,3182,3172_13847__langl-en,00.html

