Clinical trials

- What you should know

sources for trials-below

Clinical trials in humans are necessary for the testing of new and hopefully improved treatment options. A team of researchers who've developed the treatment guidelines monitor response, side effects, effectiveness and comparison with standard therapy. These trials are used to test drugs, surgeries, radiation and combinations of treatments, as well as very new arenas such as gene therapy. Clinical trials are considered the leading edge of medicine, and though not all trials lead to improvement, many do.

Cancer trials have four phases;

Phase I

This is the riskiest as well as the most important step of drug developement, due to the fact that although the treatment has been studied in laboratory animals, most times it has yet to be tried on people. Phase1 trials test the treatment on a small patient population who have failed standard therapies. Primary goals of phase I trials are determining

-anticancer activity of the treatment

-the manner in which the drug works in the body

-effective dosages, toxic side effects and the management of these

A phase I study starts by giving a very low dose of the drug, then the dose is slowly increased as new patients enter the trial. The dose can be increased by giving more at one time or by giving the same dose more often.

Phase II

Phase II investigates the effectiveness of dosages and schedules which were determined during the phase 1 study. These trials are also usually limited to those who have failed conventional treatment and could possibly benefit with the experimental therapy, and use a slightly larger number of volunteers, though the number of patients may be increaseed if promising results are shown as the phase II trial progresses.

Phase III

In this phase the new treatment is compared to standard therapy in a randomized, controlled way to determine proof of effectiveness. Larger numbers of patients are needed because patient age, sex, race and other unknown factors could effect the results.

Two independent phase III trials must be completed before a new drug can get FDA approval and be made commercially available. The drug is compared to existing treatment, or to no treatement at all. In order to establish

a baseline, some patients receive the new treatement, some may receive the conventional treatment or placebo (appears to be a treatment, but isn't). If the new treatment is clearly safer and much more effective than alternatives, the FDA will sometimes allow this phase of testing to be omitted, putting the treatment on track for approval.

Phase IV

This phase includes continued evaluation of the treatment's effectiveness and monitoring of side effects, as well as implementing studies to evaluate usefulness in different types of disease.

Participating in clinical trials

If someone is invited by their doctor to participate in a clinical trial, it is most often the one that their doctor or hospital happens to be participating in. As Steve Dunn points out;

"...People are often not informed that there are many trials being conducted throughout the country, and that some are more far more promising than others...You should be aware that different, often very similar, versions of the same treatment can be under test in several different clinical trials at the same time. These trials can be of different phases, so you may have more options than you think. It is normal for good results in a phase II trial to be confirmed by another phase II trial before moving onto phase III trials. Such a confirming trial is a good bet. In addition, there are often several trials of small variations on a new treatment in progress at the same time. Sometimes the differences in treatment make a big difference in results, but sometimes not. If a treatment is promising then variants may also be promising, and it may happen that you qualify for a trial of a variant on a promising treatment." See CancerGuide's articles at http://www.cancerguide.org/clinical_trials.html for more information on how to determine if a clinical trial could be an option for you.

Before deciding to participate, some important questions are

-What do the researchers hope to answer in their study

-Risks vs. benefits

-Cost (some trials are free)

-How many participants needed? Already involved?

-How have the other participants responded so far

"If 19 patients have been treated, and you are patient No. 20, clearly you should ask whether the treatment worked on your predecessors. If it was not effective for all 19, researchers still need a 20th patient to complete the trial. Researchers would not be obliged to tell patients that the trial didn't work for the first 19 people, since they would only suspect the treatment was ineffective." http://www.usnews.com/usnews/issue/990524/nycu/trials.b.htm

Before agreeing to participate in any given trial, it's a good idea to get a second opinion from someone who has no involvement with the research or institution.

Advice from a Bladder Cancer Warrior:

"One's BLC treatment (traditional medicine, nontraditional, prayer, or nothing at all) is an individual choice. What is important is making decisions based on rational thought and good information. Discussions about studies, caused me to look for what is important in a study. A good site (without confusing jargon) exists . I encourage you all to look at it. It takes a little time but the time is well spent. Go to : http://www.childrensmercy.org/stats/category/StatisticalEvidence.asp

It is by Steven Simon a PhD Research Biostatistician who works for Mercy Children Hospitals & Clinics. My belief is Doctors are best at treating patients but the Ph.D's are best at constructing a valid study. It' s probably a matter of training. With statistical evidence one has to decide the strength of the evidence. What is important is how the data are collected not how the data are analyzed . Faulty collection invalidates a study Relevant inquiries include: number of patients (true randomization depends on large numbers); length of study; consistent measurements; fair comparisons (making sure the control group is identical to the treatment group); eliminating any important characteristic that would influence the outcome; how were the patients selected; matching (ensuring that the control group is of the same characteristics as the treated group e.g. sex, race, and socio-economic status) I am not trying to offend anyone about their favorite study but I do encourage you all to go to the web site it is worth the time and probably should be one of the first steps in everyone's BC education to help make rational choices." Ken Hulse

Sources for finding clinical trials (links open window to new page)

Medline Plus Has a pre-searched out list of trials for bladder cancer at this (very handy) link.

http://www.nlm.nih.gov/medlineplus/bladdercancer.html#clinicaltrials

NCI Cancer Trials Information over, and help with finding clinical trials

http://cancertrials.nci.nih.gov

Centerwatch More trial listings

http://www.centerwatch.com/

Cancer Research Portfolio, from the NCI, see the current 325 projects currently underway for bladder cancer

EORTC For the European genito-urinary oncology protocol listings

http://www.eortc.be/home/gugroup/

UKCCCR
Register of Cancer Trials UK trials

http://www.cto.mrc.ac.uk/ukcccr/home.html

CancerWEB
Excellent info source

http://www.graylab.ac.uk/cancerweb/trials.html

EmergingMed.com A matching and
referral system, designed to help you find an appropriate trial. If you
find a match, EmergingMed staff will help you schedule your initial appointment
with the doctor. Information can be filled out anonymously and remain
password protected. http://www.emergingmed.com