Clinical Trials The Basics

Canadian Breast Cancer Network
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Understanding more about clinical trials and how they work may help individuals with metastatic breast cancer decide if they are an option for them. The following provides some basic information about clinical trials to help individuals be better prepared to discuss this option with their healthcare team.

What are clinical trials?

Clinical trials are done to determine the safety and efficacy of potential new treatments. All treatments available in the market today have been tested through a clinical trial program and authorized for sale by Health Canada.

What should participants know?

Procedure

Participants are not guaranteed to receive the study medication. Trial participants are randomly given either the current standard of care, the study medication being tested in a study or a placebo if there is no available medical therapy for the disease. They are never deprived of treatment in the metastatic clinical trial setting even if they elect to withdraw from the study. During the trial, neither the participants nor the researcher will know the treatment they are receiving unless the treatment produces adverse medical results. If side effects are severe, the clinical trial may be stopped. Also known as “blind” or “masked” studies, research teams and participants will not know what treatment is administered as to not inject bias in reporting and influence the trial’s results. The participant’s name will also never appear in a report once the study is published. Participants may withdraw from the clinical trial at any time.

Asking the Right Questions

All clinical trials provide information on the intent of the study. However, there are several questions participants should ask the healthcare provider conducting the study before joining a trial, such as:

- What is the purpose of the study?
- What type of patient is eligible?
- Has the medication been tested before?
- What are the potential side effects and expected benefits compared to the current approved medication?
- How and how often will the medication be given?
- How long will the trial run?
- Will there be travel involved (and expenses reimbursed)?
- How often will participants be monitored?
- When will I know if the medication is working?
- Will I be able to stay on the medication after the trial has ended?

Asking these questions is part of the process of informed consent as participants will be required to fill a consent form at the start of the clinical trial.

Eligibility

Each clinical trial will have eligibility criteria to determine if an individual is suitable to participate. The trial will want participants to have similar characteristics to preserve scientific accuracy. In addition, these criteria help researchers understand who will benefit most from a potential new treatment. Criteria can include age, sex, type and stage of cancer, overall health, whether the individual has had previous cancer treatment and what type, and proximity to the testing centre, among others.

What are the benefits and risks?

Participating in a clinical trial may allow individuals to gain access to research treatments before they become available to the public, as well as access to extra follow-up care and many check-ups. A clinical trial may be an option for those whose metastatic breast cancer type has few other treatment options.

It may turn out that the study medication is not effective or it may not be better or worse than the current drugs available in the market and may produce adverse side effects or other risks that are not yet known. Participants will also need to commit to several hours of follow-up to stay in the trial.

How can people with metastatic breast cancer find clinical trials that may be right for them?

For more information on clinical trials, please visit www.cbcn.ca.

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