Clinical Trials

What exactly is a clinical trial anyways?

-A clinical trial is a research study involving human volunteers. The purpose of a clinical trial is to gain new knowledge about a health issue, such as cancer. The information can then be used to help detect, diagnose, treat, or even prevent future cases.

*Remember, clinical trials are voluntary and require your informed consent. Make sure you are fully aware of the risks and procedures associated with each clinical trial. If any point in the trial you feel uncomfortable, like the treatment isn't working, or that participation is causing you harm, you have the right to discontinue involvement with the study.

-For testicular cancer, clinical trials are being conducted that aim to:
- -identify causes and risk factors
  - -Is it genetic? Environmentally induced? A result of testicular trauma?
- -examine relationships between TC and other health issues
  - -Is TC related to obesity? HIV status? Other cancers and diseases?
- -better treat testicular cancer
  - -Are new treatment methods superior to old? Do they work well in conjugation with already established treatment methods? What dosage is appropriate?
- -better screen for TC
  - -Are there better ways to detect testicular cancer and find it earlier? Are there any indicators of TC before symptoms occur?
- -prevent testicular cancer
  - -Are there any behavioral or medicinal habits that could prevent TC from occurring? From reoccurring?
- -create check-up/routine plans for TC survivors
  - -How often should a patient in remission go in for check-ups to ensure that TC is detected as early as possible if relapse occurs?
  - -What lifestyle changes should a patient make following the end of treatment?
- -manage side effects of treatment
  - -Can new medications help alleviate side effects?
  - -Does diet impact side effects?
  - -Can behavioral changes influence side effects?
  - -Do new treatment methods have better or worse side effects?
  - -Do the benefits of treatment outweigh the side effects?
- -how do outside factors influence TC outcome?

-Social support, stress, religion, attitude, community involvement, marital status, whether or not the patient received counseling, etc. ---how are all of these factors associated with outcome and well-being?

-Questions you might have about clinical trials:

1. Are they safe?

-Before any study is conducted, it must be approved by an institutional review board (IRB) dedicated to maintaining the safety of the volunteers and making sure that the study is ethically sound. The IRB, composed of a team of physicians, community members, and researchers, also monitors the study throughout its length. If the IRB feels the study is too risky or provides no real benefit, it will not approve the study. The IRB can also terminate a study at any time if they determine that the study has become harmful to the participants or unethical. The IRB seeks to maintain the welfare of the volunteers. Ask the researchers conducting the clinical trial you are interested in about what forms of protection you will be provided.

-You also have a say in your own safety. Before enrolling, a researcher will explain to you all potential risks and benefits, and will also provide you with a thorough description of the procedures. You are required to sign an informed consent waiver saying that you understand the risks and benefits of the study. If you do not feel comfortable with the study, you are under no obligation to enroll.

-Other federal agencies and monitoring boards exist to make sure that the participants are treated humanely and safely. Do some research on the study you are interested in and see what kind of safety boards exist for it.

-Most clinical studies DO present risks. The risks may be no greater than the risks associated with your normal medical treatments in some cases, but in others, the risks may be more serious. Make sure you are fully aware of the risks of the study. Have the researcher explain everything in detail and go to your doctor for a second opinion.

2. Who conducts the clinical studies?

-Each clinical study is headed by a lead investigator, or principal investigator (PI). The PI is responsible for maintaining the safety and welfare of participants throughout the study. They usually have a staff of doctors, nurses, research assistants, and other health professionals who help them carry out the study.

-The clinical trial can be funded by many different sources including volunteer organizations, academic institutions, medical institutions, pharmaceutical companies, physicians, health care providers, or government agencies such as the

Food and Drug Administration, National Institutes of Health, Department of Defense, or other departments.

3. Where do clinical trials take place and for how long?

-The location of the clinical trial depends on who is conducting the study and where they are located. You can search for trials by location. In some studies, you are only required to submit self-assessments and travel is not required. In others, you may be asked to travel to a clinic. You may be compensated for your travel and time.

-The length of the clinical trial depends on what exactly is being studied. If a researcher just needs a blood sample, you may be in and out in an hour. Other studies require monitoring over time and can last several months.

** Make sure you know all of the specifics of a particular clinical trial before consenting.

4. Do I have to pay to take part in a clinical trial?

-In some cases, the treatment provided through the clinical trial will be free of charge for both you and your insurance provider. Typically, any test, procedure done specifically for research purposes will be covered by the study. Insurances will be billed for what is "considered standard of care". In other cases, your insurance may be billed for the medications, devices, or treatment administered in the study. It is important to check with your insurance before consenting to the study---if your insurance doesn't cover the charges, the bill may be sent to you personally. The informed consent packet will go over any fees associated with the study. If you still have questions, be sure to ask---You don't want any surprise charges!

-While some studies may bill you, others may actually pay you for participating. To maintain the validity of the study (to avoid people signing up just because they're getting paid), researchers are not allowed to pay the participants any amount large enough that would motivate people to be included in the study. You may receive appropriate compensation for your time, travel, meals, parking or child care, though. The compensation varies from study to study, so ask about the specifics.

5. What are the advantages of taking part in a clinical trial?

-You have access to new treatment plans and procedures that are unavailable to the general public. You are also given expert medical care during your time at the treatment facilities.

-The treatment methods may be effective for you and the side effects could be less severe than those resulting from normal treatment.

-By participating in the study, you are contributing to new medical knowledge that may be life-saving for you, or for future generations of TC patients.

-For patients who are no longer responding to traditional treatment, a clinical trial can provide some hope, but remember this is not guaranteed, so it is important to do so with caution.

6. What are the risks of taking part in a clinical trial?

-Any treatment method, including those commonly used, poses some type of risk. Ask how the risks of the treatment provided in the study compare to the risks of already-in-practice treatment methods.

-Risks can range from mild side effects to potentially life-threatening consequences. Be sure to ask about any uncertainties you have about participating with both the researchers and your doctor.

-The study may require time in the hospital, which may increase your chances of acquiring an infection.

-Another potential risk may be that the study treatment is not effective for you.

7. Can I drop out of the study before the trial is over?

-Without participants completing the study, scientists cannot validate their conclusions, so when people drop out of studies, it does hurt the results of the study. Make sure you are interested and fully informed before signing up.

-With that being said, you do have the right to withdraw from the study at any point. If you feel that you are not being treated ethically or that the treatment is causing you harm, you are NOT obligated to continue. You should never feel forced to participate in a clinical trial---it should always be YOUR choice! In the end, it is most important to do what is best for YOU.

Talk with your doctors and family about the pros and cons of a clinical trial to see if it is right for you. If possible, have a friend or loved one accompany you to your appointments. This can ensure that you are both interpreting the information in the same way and that all questions are answered.

Questions to ask if offered participation in a clinical trial:
-What are the goals of the study/What information is this study hoping to gain?
-How long will the study last?

-How often will testing or visits to clinics be? Will I be hospitalized?
-What will I be responsible for?
-Do I have to pay to participate?
-Does my health insurance cover any of the charges?
-Will travel be required?
-Will I be compensated for my time or travel?
-What potential side effects and risks have been identified?
-Is this trial riskier or safer than other clinical trials studying the same thing?
-What are the short and long term benefits?
-Has an IRB approved this study?
-Who else has reviewed the trial?
-Who is funding the study?
-Who will monitor the safety and well-being of participants throughout the study?
-Who can I contact if I have questions?
-Will participating in this study interfere with my treatment?
-Has whatever is being studied in the trial been tested before?
-Will I know which group in the trial I am a part of? (Intervention vs. control)
-Can I quit the study after I'm enrolled?
-What happens if I'm negatively affected by the study intervention?
-Will I be able to see results of the study?
-Will the researchers provide my doctor with information that may be relevant to my treatment?

*This list is just general questions. If you have more specific questions or concerns, be sure to address them with the research team and your doctors.

-If you are interested in participating in a clinical trial, your doctor may be able to refer you to one in your area or you can check sites such clinicaltrials.gov (published by the National Institute of Health) to see what studies are being conducted. You can search by topic (i.e. testicular cancer) and by location. Check the eligibility requirements to make sure you fit the enrollment requirements. It is advised to get a medical professional's opinion before beginning a clinical trial and be sure to notify your doctor if you do decide to take part in a trial.

Be advised that even if the intervention in a clinical trial works for someone else, that does not guarantee that it will be successful for you (and vice versa).

Some people with cancer that is no longer responding to treatment decide to participate in clinical trials to help future generations.

Participating in a clinical trial is a personal choice and is not right for everyone. Get medical advice and family member's opinions. Always make sure you are fully informed before making a decision!

(all sources have been cited on citations page)
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http://www.clinicaltrials.gov/ct2/about-studies/learn#Questions
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