Clinical Trials: The Future of Cancer Care

Leon Hwang, MD

CANCER SURVIVOR DAY
What is a Clinical Trail?

A clinical trial involves research using human volunteers, also called participants.

• It is intended to add to medical knowledge.

• There are two main types of clinical studies:
  1. Clinical trials, also called interventional studies
  2. Observational studies
Phase I Trails

- Studies conducted with volunteers and emphasize safety.

- Goal is to find out drugs most frequent and serious adverse events are and how the drug is metabolized and excreted.

- Small group [20-80] for 1st time to evaluate safety and determine safe dosage range & identify Serious Events
Phase II Trails

- Studies that gather data on effectiveness (whether the drug works in people who have a certain disease or condition).

- Safety continues to be evaluated and short-term adverse events are studied.

- Drug or treatment given to larger group [100-300] to confirm effectiveness, monitor Serious Events, and further evaluate safety.

- No placebo’s involved.
Phase III Trials

• Randomized trials comparing new therapy to standard therapies.

• Drug or treatment given to even larger group [1,000-3,000] to fulfill all of Phase II objectives.

• Compare it to other commonly used treatments and collect data that will allow it to be used safely.
Important Terms Defined

- **Randomized**: A computer will randomly choose which treatment patient will receive. This decreases bias.

- **Nonrandomized**: All patients receive the same treatment.

- **Protocol**: Study design - instructions

- **Blinded**: Participants do not know if in experimental or control group

- **Double Blinded**: Participants AND staff do not know group assignment

- **Placebo**: Inactive pill with no therapeutic value
What you need to know before enrolling in a trial

• What are the side effects (adverse effects)
• Time commitment
• Benefits & risks
• May withdraw at any time
• Enrollment 100% voluntary
• What are the other options
Institutional Review Board

IRB responsible for such tasks:

• Review research to ensure that potential benefits outweigh risks
• Develop and issue written procedures
• Review research for risk/benefit analysis & proper protection of subjects
• Issue written notice of approval/disapproval to the Investigator
• Review and respond to proposed protocol changes submitted by the Investigator
Why Patients enroll in Clinical Trails?

Why Some Participate?

- Give back to society
- Exhausted all other treatments
- Health care services
- Payment & incentives
- Hope

Why Some Do Not?

- Mistrust of studies
- Do not want to be “guinea pig”
- Do not meet criteria
- Cannot give up time for study visits
- Not getting Standard of Care treatment
Pro’s and Con’s of enrolling in trails

Pro’s
• You may benefit from the new drug.
• You will get extra visits and tests
• More health professionals involved in your care.
• Another opinion on your care
• Patients in trials live longer

Con’s
• You may have no benefit and unneeded side effects
• You will get extra visits and tests
• Delays to treatment b/c of need for drug free period, new doctors, extra tests for eligibility
• Learning to navigate new health care system
• Your treatments will be on a rigid schedule, not tailored for you
2. Enter cancer type and stage, zip code, mile radius and search.
3. Click hypertext for details, such as location
Hopkins or National Institute of Health (NIH)?

• NIH does more basic research
• NIH is closer (Bethesda vs. Baltimore)
• NIH is strong in lymphoma, immunotherapy, prostate cancer, Phase I’s, Thoracic Surgery
• NIH is free, needs no referrals. You can self refer.
• NIH Toll Free #: 800-422-6237
Kaiser Permanente Resources:
http://kpstudysearch.kaiser.org
Your oncologist’s role in clinical trials

• Your oncologist would be happy to look for trials for you
• Your oncologist can get you into trials quicker
• Bring records and film disc’s to and from the research trial.
• Exchange phone numbers, emails, fax numbers for oncologist & trial doctors. Have them send records of important notes.
• Contact your oncologist when ready to return
Kaiser Permanente Clinical Trails

Breast Cancer Trails

1. BREAST-ALLIANCE A011401
2. BREAST-ALLIANCE A011104/ACRIN 6694
3. BREAST-SWOG S1207
4. Triple Neg. Invasive BREAST-NRG BR003
5. aBC-NOVARTIS COMPLEEEMENT-1
   CLEE011A2404
Kaiser Permanente Clinical Trails

Colon or Rectal Cancer and Prostate

- COLON or RECTAL CA-SWOG S0820
- PROSTATE- mHSPC-ASTELLAS 9785-CL-0335

ARCHES

Myeloma

- MULTIPLE MYELOMA- ECOG E3A06
- GLIOMA- ALLIANCE A221101
- MELANOMA- SWOG S1404
Please Consider Clinical Trials As Part Of Your Cancer Care

- You will receive cutting edge therapy
- You will get extra exams, nursing care, and closer monitoring
- You will be helping others who will learn from your experience. This is even more important for minorities who are under-represented in studies
- Your care will be “proof-read” by an outside agency
- Different studies are available for every phase of your treatment and change monthly
- Speak to your oncologist if you are interested
Questions?