Chemotherapy and Advances in Clinical Trials

Mark Agulnik, MD
Associate Professor in Medicine – Hematology / Oncology
M-Agulnik@northwestern.edu
Sarcomas

- Sarcomas constitute a heterogeneous group of rare solid tumors of mesenchymal cell origin with distinct clinical and pathological features; they are usually divided into two broad categories:
  1) Sarcomas of soft tissues (including fat, muscle, nerve, blood vessels, and other connective tissue)
  2) Sarcomas of Bone

- Sarcomas collectively account for approximately 1% of adult malignancies and 15% of pediatric malignancies.
What is the Northwestern Approach

1) Integrated Surgical and Medical Oncology Sarcoma Clinic (Tues/Fri)

2) Complete and comprehensive Clinical Trial Portfolio

3) Integrated adult and pediatric Sarcoma Tumor Board

4) Robust exposure nationally and internationally: NCCN, CTOS, AJCC, Alliance, SARC

5) Founding member of Midwest Sarcoma Trials Partnership
What’s a Clinical Trial?

Clinical trials are carefully designed medical research studies conducted with people that:

• Test promising diagnostic, treatment and prevention methods
• Attempt to answer scientific questions
Who Sponsors Clinical Trials?

• Pharmaceutical Corporations:
  Investigational New Drugs

• Academic Medical Centers:
  Investigator Initiated Trials

• National Cancer Institute:
  United States Cooperative Groups
Types of Clinical Trials

- Interventional: Treatment, Prevention
- Quality of Life
- Screening
Why Clinical Trials are Important

• Advances standard-of-care for cancer treatments
• Increased understanding of disease process
• Required by FDA prior to approval
What Have We Learned?

• Race, gender and ethnicity can be risk factors for certain cancers
• Discovery of Human Genome Project, 2002
• Emerging therapies lead to targeted treatments, often with fewer side effects
Stages in the Development of Medicine

Laboratory Research

Animal Testing

Clinical Trials in Humans

- Phase I
- Phase II
- Phase III
- Phase IV
Clinical Trial Phases

• Phase I - First studies in people to test safety
• Phase II - Is the drug effective?
• Phase III – Compares investigational drug with standard-of-care treatment
• Phase IV – Ongoing safety data, usually post-FDA approval
Process of Clinical Trial Initiation

- Protocol Submission to Academic Center
- Scientific Review Committee
- Institutional Review Board
- Trial Initiation and Patient Enrollment
Myth #1: “I might receive a placebo instead of active treatment”

Fact: Placebos are rarely used in cancer clinical trials- unless there is no established standard of care.
Myth #2: “Clinical trials are not safe”

Fact: Each step in drug development is highly regulated to ensure the safety and protection of research participants. Remember, all of today’s best cancer treatments were once clinical trials.
Myth #3: “If I consent to a clinical trial, I lose the chance to receive more effective standard treatments”

Fact: Standard treatments are always available to patients. Patients may withdraw participation in a clinical trial at any time, and for any reason.
Myth #4: “Participating in a clinical trial means there is no hope”

Fact: Clinical trials are often available for all stages of cancer, including newly diagnosed/untreated
How Do I Enter a Clinical Trial?

- Eligibility criteria

- Informed consent process:
  Opportunity to learn about potential benefits and side effects
  Not a contract!
  Open dialogue between patient and clinician, and clinical team
Potential Benefits

- Gain access to advanced treatments
- Potential for extending treatment options
- Study treatment is at no cost
- Contributing to the advancement of medicine
Potential Risks

- Potential for unknown side effects of study treatment
- The study may require additional time than standard therapies
- The study treatment may be ineffective
Who is Watching Out for Patient Interest?

• The Food and Drug Administration
• National Cancer Institute
• The Institutional Review Board
• The Physician/Investigator
Know Your Options- Ask Questions

• What are my other options?
• Who put the study together?
• Where is the trial being conducted?
• What will I get out of this study?
• What are the risks to me?
• How long will the study last?
• What tests are involved?
How do I find a Clinical Trials for Sarcomas?

1- Ask your doctor for help
2- Reach out to an academic medical center in your area
3- Go online:
   • WWW.CLINICALTRIALS.GOV
How do I find a Clinical Trial for Sarcomas?

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world. Learn more about clinical studies and about this site, including relevant history, policies, and laws.
Drugs Approved for Soft Tissue Sarcoma

- Cancer drugs approved by the Food and Drug Administration (FDA) for soft tissue sarcoma:
  - Dactinomycin
  - Doxorubicin
  - Imatinib
  - Pazopanib

- Drugs commonly used include:
  - Ifosfamide
  - Dacarbazine
  - Gemcitabine
  - Taxotere
  - Paclitaxel
  - Vincristine
  - Temozolomide
  - Sorafenib/Sutent
Drugs To Be Approved for Soft Tissue Sarcoma

– Yondelis
– Eribulin
– Evofosfamide
– Olaratumab
– Aldoxorubicin
– GPX-150
Questions, Comments or More Information:

• Mark Agulnik, MD
  • Associate Professor of Medicine
  • Robert H. Lurie Comprehensive Cancer Center
  • Northwestern University
  • 312-695-0990

• Sara Duffey
  • Clinical Trial Recruitment and Education Specialist
  • Robert H. Lurie Comprehensive Cancer Center
  • Northwestern University
  • 312-695-1102
  • s-duffey@northwestern.edu