

Clinical (therapeutic) Research Defined

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I'm so excited about research. Research is the means by which we can prove therapies are beneficial. Without it, we are left with medical quackery. For years the conventional medical establishment has engaged in thousands of research studies for the benefit of many more patients. At Saint Anthony's Medical Center we are currently running National Cancer Institute sponsored cancer trials in a variety of cancers. These are the same exciting trials that are run at prestigious institutions such as Washington University in St. Louis, MD Anderson Cancer Center, Memorial Sloan Kettering Cancer Center and Mayo Clinic. Whenever you have the chance, you should consider entering on a clinical trial. These "experimental therapies" are the "standard therapies" of tomorrow.

Therapeutic research is performed in three phases, phase I, phase II, and phase III. These are very different trials, so you should know what each means. A phase I trial involves the first human use trial of a medicine or device. These are usually reserved for patients that have no other options. These are not appropriate for many patients. A phase II trial involves a promising new therapy. These are studies designed to define how effective a medicine or device is. The most effective and promising treatments are then sent on to the next phase. A phase III trial compares the current "standard of care" treatment with a promising new therapy from a phase II trial. These are the trials that determine which therapy is best and which will be the new standard. A phase III trial has the least risk because you know you are getting either a standard therapy or one thought to be better.

There are some other terms that are important; randomized, blinded and placebo controlled. A randomized trial means a computer determines which treatment arm you receive. This eliminates the researcher from choosing and removes any bias. A blinded trial is one in which the patient and sometimes the researcher are not allowed to know which treatment is being given. This prevents the patient and researcher from altering their perception of the results, good or bad, based on which therapy they think they are receiving. Placebo controlled means a prescribing a dummy pill or treatment so the patient and researcher can't guess which treatment is being given. This may seem silly, but the outcome of trials can be affected by which treatment of patient thinks she or he is getting.

If you are unfortunate enough to become ill and are offered a research study, please consider it. A study is not for everyone, but many people have been helped by those who were considerate enough to enter onto a clinical trial. We owe a great debt of gratitude to those wonderful patients.