

Doctoral Degree Scholarship in Cancer Nursing

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Abstract:

Clinical research is the process by which researchers test new therapies to learn which ones will be useful and safe as medical treatments. Once a new therapy is discovered, it is first tested in animals and then in a series of clinical trials in humans, all of which will lead to government approval for the use of the therapies determined to be safe and effective in medical practice. The process of developing of new therapies is the same for every illness, including children with cancer. The four phases of clinical trials of new drugs are described by the National Library of Medicine as follows:

- Phase I: Researchers test a new drug or treatment in a small group of people for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.
- Phase II: The drug or treatment is given to a larger group of people to see if it is effective and to further evaluate its safety.
- Phase III: The drug or treatment is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely.
- Phase IV: Studies are done after the drug or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use.

While phase I clinical trials are necessary to develop new, more effective therapies for children with cancer, the children participating in these trials are considered incurable and they endure extra medical procedures and may suffer side effects from the unproven therapy. Parents enroll their child with advanced cancer in these trials in the hope of finding a cure, or of at least buying more time for their child. Phase I clinical trials are controversial in children with cancer because in the search for an effective treatment for their child, parents may seek and consent to any therapy, even those with significant risks. Phase I trials are unlikely to help the child, because they are designed primarily to determine the safe dose and identify side effects of the therapy. The challenge for researchers is to ensure that the need to develop improved treatments for childhood cancers has as little negative impact as possible on children and parents participating in phase I clinical trials.

This study involves interviewing parents whose children with cancer participated in a phase I clinical trial in order to hear their experiences; to understand parents' experiences of having their child enrolled in a phase I clinical trial and to understand parents' perspectives of what it was like for their child to participate in a phase I clinical trial. This study will be the first to develop an understanding of the experiences of parents with children who participate in these trials, and will provide the foundation for future research focused on optimizing parent and child experiences in phase I clinical trials.