

**Clinical trials-for pediatric**

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Abstract

Clinical word origin from clinic, from the French Clinique's and from the Greek klinike, and refers to the practice of caring for the sick at the bedside. The term of trial mean to the action or process of putting something to a test or proof. Hence, narrowly, a clinical trial is the action or process of putting something to a test or proof at the bedside of the sick. However, broadly it refers to any testing done on human beings for the sake of determining the value of a treatment for the sick or for preventing disease or sickness. Today there are only a handful of drugs approved by the U.S. Food and Drug Administration (FDA) to treat hepatitis B, C or D in adults. There are even fewer for children. Most drugs used to treat children with viral hepatitis-related liver disease have been formally tested only in adult patients. Just two or three drugs have been fully tested in pediatric clinical trials involving children and adolescents ranging in age from infancy through age 17. In general, more than 60% of all drugs used of children today have not been tested in pediatric clinical trials. According to American Academy of pediatrics, only a small fraction of drug and biological products marketed in the United States, including Ritalin used to treat attention deficit disorder in children and albuterol nebulizers used to treat asthma in children, have had extensive clinical trials performed in pediatric population.

Key-Words: Clinical, FDA, Children, Human, Age**Introduction**

Clinical trials initiated since 1960 have had a profound effect on the overall survival of children with leukemia and solid tumors. In India many drugs are used in to the children or we say apply in the children. If we talk about in India most of the drug used to treat children with viral hepatitis related liver diseases have been formally tested only in adult patient, just two or three drugs have been fully tested in pediatric clinical trials involving children and adolescents ranging in age from infancy through age 17.

In India many cases especially in the treatment of children with hepatitis "C" with serious liver diseases doctors are permitted to use drug that have only been tested and approved by the FDA for use in adult and some other many steroidal drugs.

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Pediatric clinical trials begin

One ethical issue pediatric researcher's face is the fact that clinical research involving some risk to the subjects. Research procedure range from techniques involving higher risk such as chemotherapy and surgery risk is greatest in the early phase of clinical research. At what point in a drug development should research in children begin? The ICH of technical requirements for registration of pharmaceutical for human use makes several suggestions regarding the inclusion of children developments program of medicinal products. As research subject children have special needs because of their vulnerabilities and developmental peculiarities. Doctors involving in research on children must respect the autonomy and the individually of children, be aware of children's apprehension about medical procedure and acknowledge the fundamental biological difference between adults and children.

The need for clinical research in children

In 1989 the United Nations general assembly approved a convention on the rights of the child. The following four principles articulated in this declaration are of fundamental importance in pharmaceutical studies.

- ✓ All human rights apply to children without exception.

- ✓ All intervention must have the child's best interest as primary consideration of the highest priority.
- ✓ Children have the right to the highest attainable level of health.
- ✓ Children have right to obtain information and the right to respect of their opinion.

The FDA, EMEA and other authorities state that research in children should be support and encouraged the committee for proprietary medicinal product (CPMP) recommends the following categorization of products to be studies in pediatric clinical trials.

- ✓ Medicinal products for diseases affecting children exclusively such as surfactant in neonates.
- ✓ Medicinal products intended to treat disease occurring in adults and children for which there is currently no treatment.
- ✓ Medicinal products intended to treat diseases that mainly affect children or have a different natural history in children or are of particular gravity in children.
- ✓ Medicinal products to treat a disease occurring in adults and children for which there is insufficient knowledge of toxicity in children.

When a pharmaceutical company develops a new drug it typically spends years developing the compound and testing it in a laboratory setting on human and animal cell. Then the drug is tested on living animals. If these tests are successful the pharmaceutical company provides its data to the FDA and request permission through an investigational view drug in human in clinical trials, also known as medical research or research studies. When it has FDA go ahead clinical testing of experimental drug is conduct in three phases, each phase involves a larger number of people. Once the FDA has granted a view drug approval, pharmaceutical company also conduct post marketing studies.

The FDA is now developing new guideline to force pharmaceutical companies to accelerate drug testing in children to ensure pediatric safety and effectiveness. In India over 75% of medicines used in children are not licensed for use either for the disease states or for the age groups.

During past 22 years medical and legal experts have studied the issue surrounding a child's participation in clinical trials in the eye of the law children 17 and younger are not adults and parent or guardians must grant legal permission for their participation after reviewing all the possible ramifications of the trials. This is called the informed consent process.

The reason FDA gives Physicians Latitude in using drug that have been tested only in adults is to hasn't testing of life-saving drug in children and adolescent. Once a drug has been FDA approved any physician can prescribe it, Dr. Brady added it doesn't matter that most drug are approved because of adults trials most drugs used by pediatrician were never tested in pediatric trials. In the case of lamivudine it had a good safety record in kids with HIV, so i was even less hesitant to use it in children with hepatitis B outside the pediatric trials.

Annually about 7500 American children younger than the age of 15 are diagnosed with cancer. An almost equal number of adolescent between 15 to 21 years of age also will be develop cancer consider for example that the year 2000, the European union had about 7.5 million children and 45000 pediatricians but only 12 clinical pediatric pharmacologists. When a clinical trial involves researchers and doctors in several hospitals and research center across the country a data safety monitoring board may be appointed to keep track of the data to ensure participants safety.

Good Clinical Practice (GCP) issues

No child should be participating in a study unless a benefit to children in general will result. The ICH notes that the benefit to the individual and the benefit to the group must be balanced as follows

"The ethical imperative to obtain knowledge of the effect of the medicinal products in pediatric patient has to be balanced against the ethical imperative to protect the individual child in clinical studies and respect his/her integrity and personal dignity."

GCP helps maintain the balance by ensuring that subjects are properly protected in research studies; studies are based on good science well designed and properly analyzed and study procedure are properly undertaken and documented who take part may be at the risk, the data may be unreliable or unusable and study should be rejected by the ethics committee.

GCP follows the general principal of medical ethics

- ✓ Respected for life, human dignity and personal autonomy.
- ✓ Beneficence (do some good)
- ✓ Non- maleficiences (do no harm)
- ✓ Justice

From these ethical principles general guideline for good clinical practices in pediatric research can be derived.

Some ethical issue that would arise in such a trial

- ✓ What are the pharmacokinetics and pharmacodynamic of such a dose? Insulin distribution and metabolism would have been studied.
- ✓ Assuming only about 10% of an inhaled dose is absorbed would radio-isotope studies of insulin deposition be required.
- ✓ Are there potential deleterious effects of such a large dose, such as antibody formation?
- ✓ Children with diabetes of 5 to 10 years duration would be very willing to participate. They would likely have a good appreciation of the issue involved. They would probably be willing to risk potential side effect in exchange for perceived benefit (absence of injections) would it be appropriated to include children aged 12-16 years in such trials?

At this time and in the future we can expect pediatric oncologists to play a significant role in translational research to clinical pediatric oncology practices.

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