Mini Review

Annals of Clinical Trials and Vaccines Research

Perspectives of Clinical Research

Abstract

Published research often addresses aspects related to "statistical significance" but fail to address the clinical and practical importance and meaning of results. Our main objectives in this article are to investigate the merit of common measures of Effect Size in statistical research and to highlight the importance of the simple Relative Risk ratio. In this article we present data where we consider two widely utilized effect size measures (Cohen's d and Pearson's r) in relations to relative risk. We conclude that probability analyses of risk surpass the most commonly used statistical approach used in clinical trials today and should thus be the preferred compared to the misuse and misunderstanding of reporting for instance p-values.

Keywords: Good Clinical Practice (GCP) • Clinical Monitoring Clinical Trial Management System (CTMS) • Electronic Data Capture (EDC) • Clinical Trials • Clinical Research • Protocol • Clinical Development • CRO Management • Oncology • Clinical Research Associates • Clinical Data Management

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Introduction

According to 2010 figures, about 7.6 million children under the age of five die each year [1], of which 2.4 million die from vaccine-preventable illnesses. [2] This problem is exacerbated by the lack of effective treatments for many infections. Obviously, new, cheaper and improved vaccines are needed now and in the future. Vaccines have several characteristics over medicines. Unlike therapeutic molecules, vaccines play a prophylactic role against certain infections. The target group is healthy people, mainly children and toddlers. As a result, adverse events are less tolerable. In addition, vaccines are highly complex substances derived from living microorganisms, and their quality and safety must be proven on a batch-by-batch basis. Of course, these factors have some impact on vaccine clinical trials. Here are some of the current ethical issues in clinical trials of vaccines.

Pediatrics Research

Most vaccine trials are conducted in children, some in infants and even in newborns. This is where you want to catch your child to prevent infection. However, children alone cannot agree, and vaccinated people must accept the consent of their legal guardian. Children are also expected to experience more side effects than adults. For these and many other reasons, there is a general consensus that vaccination studies in children are at least largely unethical if the corresponding studies can be performed in adults. However, the main problem with this is that many infectious diseases are characteristically only childhood diseases, or at least especially harmful to the youngest. Therefore, we must seek a difficult balance between the true and perceived needs of vaccines in the pediatric population. CIOMS said, "Before conducting a study with a child, researchers need to make sure that: – The study may not be done in adults as well. The purpose of the study is for children. To gain knowledge related to health needs. "[3]

Parental consent

Parents and guardians of children may have little or no understanding of research attempts than elsewhere in developing countries. They may not be familiar with concepts such as "informed consent" and "confidentiality" and may not understand the scientific terms and processes associated with the test, including randomization and the use of placebo. I have. However, these parents are asked to agree on behalf of their young child or explain to their older heirs (children) what is happening in the process. Another issue is the consent of the appropriate statutory agent in the absence of parental consent. Recently, a vaccine demonstration project was carried out in India. The investigation was initiated after reports of several dead. No dead were found.

Due to the vaccine, some residents have questioned the consent of the home director. [4]

Process need

Before starting a study in children, it is necessary to demonstrate that it is essential to use children to demonstrate the safety, immunogenicity, efficacy, or efficacy of the vaccine. Such attempts are not guaranteed if the child comes from a population whose particular illness is not a problem. Malaria vaccines may not be immediately tested in Europe and North America. It is essential that socio-economic inequality between developed and developing countries is not abused. That is, children in poor countries are not required to take the risk to produce vaccines that primarily benefit them for financial or other reasons. Friends come to developed countries. At the same time, research aimed at reducing health inequality in developing countries and benefiting vulnerable pediatric populations should not be hindered.

Control selection: If a good vaccine is already in use in another country or community that is nearly comparable to where the study is planned, then that vaccine should be used as a control. If such a vaccine does not exist, a placebo "vaccine" can be used if the setting is fully explained to the participants, their families, and the community. Placebo controls are ethical if no vaccine candidate has been proven for the indication being tested [5, 6].

This change in attitude means that the placebo recipient will receive a real vaccine later-but all of this needs to be explained to the participants in words they can understand. Instead of using a placebo, give another vaccine that provides equal benefits for another disease, or more easily for similar diseases caused by other drugs. This was the first vaccine against bacterial meningitis (caused by Neisseria meningitides and H) in Finland in the 1970s. Influenza) is being tested in children [7]. What was important here was that these two types of meningitis were equally common in this community. For some vaccines, the choice is not difficult as there has been no effective intervention so far. B. Malaria or HIV vaccine.

An exceptional approach was taken in Indonesia between 1998 and 2002. [8] Half of the children were vaccinated with the conventional DTP (diphtheria-tetanus-pertussis) vaccine, and the other half were vaccinated with DTP containing hemophilic influenza type B (Hib) components. Therefore, not all children are on an equal footing, but lack of data on disease burden and vaccine efficacy in the region, this study will determine whether to introduce Hib vaccination in Indonesia. The setting was considered legitimate because it was considered useful for whether or not it was introduced, and for the entire region. If you measure only immunogenicity (antibody production) instead of clinical efficacy, the balance rule becomes loose. Comparator vaccines may be more useful as "compensation" for children in the control group of studies. For example, a meningitis C-conjugated vaccine in the pneumococcal vaccine test or a rabies vaccine in the Japanese encephalitis vaccine test will not restore balance, but will benefit children who would not otherwise be vaccinated.

Age escalation: Gradual reduction in age means that Phase I and Phase II trials are conducted first in adults, then in older children, and finally in infants, if relevant. Disease epidemiology, vaccine risk\benefit for each age group, and safety profile are factors that need to be considered in escalation. However, if the new vaccine is intended for infants only, trials in older children may reveal these unwanted risks without benefiting the

"old" vaccine. Rotavirus vaccines are a good example of this category. Adult participants may not be useful in efficacy studies, but may be available in early studies.

Restrictions on informed consent

Obtaining informed consent in developing countries should be seen as a process that begins with a voluntary decision to present its own challenges and participate in research. Decisions should be made informed before participating in a study. Informed consent forms are often uneducated, or in the case of children, simple enough to be understood by parents or guardians, but with concepts, potential risks and benefits, and placebo or other placebo. Compensation for injury or death resulting from comparative medication, care provided, and research. It is important to be clear that you can stop studying at any time without explaining why. If the status of the study changes significantly, the informed consent form should be modified accordingly and the entire study should be discussed with those who are already enrolled. Then you need to get new consent. The problem of getting valid consensus is greater in developing countries where people may not be familiar with scientific research, concepts and vocabulary. Therefore, expectations may be unrealistic. The complete autonomy of an individual can be compromised by the cultural and / or gender norms of society, or even by the pressure of family or couple. All of these challenges become even more complicated when research looks at children.

Child consent: For children, every effort must be made to explain the possible risks (inconveniences, time promises, etc.) and benefits in a language that the child can understand. Investigators need to document their children. I agree Community approval

Informed consent can be culturally sensitive and may require family or community discussion, but community informed consent should not be considered a substitute for personal informed consent. There can also be tensions between the ethical responsibility of maintaining an individual's confidentiality and the cultural norms that encourage "sharing confidentiality." To the extent of confidentiality, it may be helpful to have an impartial witness / observer present during the verbal consent, especially if verbal consent is required rather than signed consent. Such witnessed consent must be recorded in the case file.

Excitation potential: Improved medical care during research can have incentives and impacts on willingness to participate. In fact, study participants often accept studies in the belief that they will receive improved treatment. It is important to explain that participation does not necessarily guarantee protection against illness. For studies using placebo, it is necessary to explain the overall design and importance of randomization, including the possibility that participants will fall into the placebo group. You need to describe the care or other services provided. Another concern is that if parents see an opportunity for financial benefit, they may encourage their and perhaps other children to enrol in studies that they should not necessarily be involved in. is. Every effort must be made to avoid exploitation and minimize mental, emotional and physical harm.

Standard of care: The status of vaccine trials in developing countries is difficult due to the high disease burden and low medical standards of this community. It is necessary to incorporate the opinions of local governments and provide standard care. This means improving the health of the participants and is sustainable. These efforts require the approval of the local ethics committee. Follow-up period

Active follow-up should continue at least until the end of the study. If you experience any side effects, you will need to continue follow-up for an additional 6 months. In high mortality populations, it may be desirable to analyse long-term mortality changes and track participants over several years. We recommend that you make the passive follow-up even longer. If an existing mechanism can be used for this. Long-term follow-up can significantly complicate research and significantly increase costs. Therefore, it may be sufficient to collect only passive data. Creative aftercare should be considered for both safety and long-term protection. High-potency measles vaccines have been studied in some African countries, but long-term follow-up has resulted in higher mortality in women after vaccination [9] and the use of the vaccine has been discontinued. This important finding was established only on

the basis of long-term follow-up.

Subject screening: Screening for inclusion / exclusion criteria is very important because vaccination tests must be conducted on healthy individuals. Enrolling a child with an underlying medical condition can complicate safety outcomes. A recent vaccine test in India has revealed this problem. One death was reported in a study after an infant received an approved control vaccine. Examination revealed that the deceased child had previously been ill. [10] It is recognized that there are limits to physical screening of infants. However, every effort must be made to determine health. If in doubt, we recommend playing safely.

Conclusion

Clinical studies on vaccines need to address specific ethical issues due to the unique nature of these studies. The problem is more complicated because the study is mainly done in pediatric populations in developing countries. It is important to consider these issues when designing a vaccine study.

Acknowledgement

None

Conflict of Interest

None

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