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Research Techniques Made Simple: Interpreting Measures of Association in Clinical Research

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INTRODUCTION

Clinical research is the component of medical and health research aimed at producing valuable knowledge for understanding human disease, disease prevention and treatment, and health promotion [1]. Clinical studies include any series of studies involving interactions with patients, diagnostic clinical material or data, or populations in one of the following categories: Two-way integrated (translational) research. Clinical knowledge, detection, diagnosis and natural history of disease; and therapeutic interventions, including the development and clinical trials of drugs, biologics, devices and instruments [2]. Prevention (primary and secondary) and health promotion; Behavioral research; Healthcare research, including outcomes and cost-effectiveness. Epidemiology; And community and managed care-based research. Clinical research is important to the National Institutes of Health's (NIH) mission to improve health, extend life, and reduce the burden of disease and disability. For example, clinical studies can provide knowledge and answers about the safety and efficacy of drugs and other treatments. Both now and in the past, breakthrough scientific breakthroughs, whether healthy or sick, were only possible through the participation of clinical research volunteers [3]. Clinical research requires complex and rigorous testing in collaboration with disease-affected communities. Because NIH-supported clinical research opens new doors to advance the prevention, treatment, and cure of diseases and disorders, clinical trial volunteers are critical to that progress. Clinical research and clinical trials are often confused with medicine [4].

DESCRIPTION

This topic can be especially confusing when doctors are also researchers. If you receive care from your primary care physician, your primary care physician will create a care plan just for you. When you participate in a clinical study, you and the researcher must follow a set plan called a "study protocol." Researchers usually can't customize the plan, but the plan includes steps to follow if you're not feeling well [5]. It is important to understand that clinical trials are experiments. This, of course, means that the answer to the research question is not yet known. Participating in clinical research may or may not directly benefit you. It is important to discuss this topic with your doctor/researcher. Clinical research is often conducted in academic medical centers and affiliated research centers [3]. These centers and campuses not only provide the prestige of academic institutions, but also provide access to metropolitan areas and provide a larger pool of medical participants. In some cases, there is an internal institutional review board that oversees the ethical conduct of medical research [2]. The clinical research ecosystem includes a complex network of sites, pharmaceutical companies and academic research institutes [1]. This has increased the set of technologies used to manage clinical research data and operational factors. Clinical research management is often supported by eClinical systems that automate the management and execution of clinical trials. Clinical trials of new drugs are usually divided into four phases [4]. If a drug successfully passes Phase I, II and III, it will be approved for use in the general population by national regulatory agencies. Phase IV is a post-approval study [5]. Phase I involves 20 to 100 healthy volunteers, or those with disease or symptoms. This study usually lasts several months and helps demonstrate safety and effective dosing. 3000 participants will be included to assess drug efficacy and safety at various doses. Only 25%-30% of drugs reach the end of Phase III.

CONCLUSION

Participation in clinical trials contributes to medical knowledge. The results of these studies can make a difference in future pa-

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tient care by providing information about the benefits and risks of therapeutic, preventive and diagnostic products and interventions. Clinical trials form the basis of the development and marketing of new drugs, biological products and medical devices. The safety and efficacy of experimental approaches or applications may not be fully known at the time of research. Some studies offer participants the prospect of direct medical benefit, some do not. Most studies involve risks of injury or harm to participants, which may not outweigh the risks associated with routine medical care and disease progression. (For IRB-approved studies, the IRB determined that the risks of participation were minimal and reasonable in relation to the expected benefits.) In many studies, participant's additional procedures, tests, and evaluations may be required based on the study protocol undergone. These requirements are set out in the consent form. Potential participants should also discuss these questions with members of the research team and their usual healthcare providers.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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