Editorial

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Safety and efficacy of medications in researches

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Various websites have allowed the general population to read research articles on different subjects of treatment including osteoarthritis and osteoporosis, and other chronic diseases or syndrome. When people read that a drug is safe for the treatment of that disease, they will look for a way to use it without a prescription and without the supervision of specialist. Many drugs may be dispensed without a prescription in some countries, especially developing countries. Adverse effects of a substance may be undetectable in the exposure that fall within the therapeutic range in safety studies designed appropriately, observations and measurements used to detect toxicity in conventional animal toxicity studies, may not be evidence for human. Efficacy and safety need to be assessed in terms of categorical ratings or numerical scores, the criteria used for point assignment should be provided (e.g., definitions of point scores).

Keywords: safety • efficacy

Introduction

Systemic and topical dosage of all medications has adverse effects, adverse drug reactions, and drug interactions. The goal is to protect clinical trial participants and patients receiving marketed products from the potentially adverse effects of pharmaceuticals.

Importance of primary and secondary end points

Many studies mentioned the efficacy and safety of the tested drug, but there is no efficacy or safety parameters were found. No description of the studied parameters was neither found, nor any demographic data concerning the enrolled patients. Safety studies are those studies that investigate the potential unwanted pharmacodynamics effects of a substance on the physiological functions using the therapeutic level and above. Any clear correlation between response and concomitant treatment or between response and patient's medical history and attendant diseases should be elucidated. The means of obtaining adverse-event data (volunteered, checklist, or questioning), as should any specific rating scale(s) used, and any precisely planned follow-up method for adverse effects or reactions should be described. The primary measurements and endpoints used to determine efficacy should be precisely specified, it is preferred to examine the dose response.

Does the demographic data effects on the results?

The concentrations of drugs must be measured regarding the sample collection times and periods in relation to the drug administration time should be described. Also relation of drug administration and sampling to the ingestion of food, to posture, and the possible actions of concomitant medication/caffeine/nicotine/alcohol should be elucidated. The measured biological sample, the handling of samples, and the method of assessments used should be described. In addition to that, group data for the critical demographic, baseline characteristics of the subjects or patients, and factors arising during the study that could affect the response to treatment, should be presented. Comparison between the treatment groups for all characteristics should be displayed, also disease factors, relevant previous treatment, and concomitant treatment, factors that affect response to treatment (e.g., weight, body-mass index, lifestyle, renin status, antibody levels, metabolic status).

Did the dose prescribed calculate according to the weight of each patient?

This is an important issue in prescribing systemic pharmaceutical preparations. The dose must correspond to the weight of the patient, and mentioned in research as mg/kg.

How is the efficacy analysed?

Efficacy study is assessed according to level and method of blinding/masking [e.g., open, double-blind, single-blind, blinded evaluators, and unblinded patients and/or investigators]. Other methods of assessment include class of control(s) [e.g., placebo, no treatment, active drug, and dose-response], and study configuration [parallel, crossover]. Another method to criterion efficacy is the method of assignment to treatment [randomization, stratification]. The specific efficacy and safety variables to be assessed and laboratory analysis to be proceeded, their schedule; days of study, time of day, relation to meals, and the timing of critical measures in relation to the administration of test drug, the methods for measuring, and the investigator responsible for the measurements should be described. Characterization of the criteria for determining the efficacy; Treatment groups should be compared for all critical measures of efficacy [primary and secondary endpoints; any pharmacodynamics endpoints], in addition to the benefit/risk assessment(s) for each patient must utilized, and scale score of categorical responses. Some studies mentioned that 90-95% improvement, with no significant complications. Such comparison put the study under bias risk, and false results.

Safety study

Assessment of safety-related data can be considered at three levels: First, the extent of exposure [dose, duration, patients' number] should be tested to determine the degree to which safety can be assessed. Second, more common adverse effects and lab tests changes should be clarified, classified, compared between treatment groups, and analysed for factors that may affect the frequency of adverse reactions or events, that could include time dependence, relation to demographic characteristics, and relation to dose or drug concentration. Finally, serious adverse reactions and other significant adverse events should be identified by close examination of patients. Duration of exposure to any dose can be expressed as a median or mean, more than one month to six months. The numbers exposed to the test drug for the various durations should be broken down by age, sex, and racial subgroups, and any other pertinent subgroups, such as groups defined by disease, disease severity, or concurrent illness [1].

Adverse events occurring after initiation of study therapy (including events related to the underlying disease or represent concomitant illness) should be clarified and discussed, and should include changes in vital signs and any laboratory parameters changes that were considered serious adverse events or significant adverse reactions. Each event may then be divided into severity categories (e.g., mild, moderate, severe). Other method is divide the adverse events into those considered at least possibly related to administered drug and those considered not related, or use another causality scheme (e.g., unrelated or possibly, probably, or definitely related).

The listing should be prepared by investigator and by treatment group and should include the following information: patient identifier, age, race, sex, weight, height, location of case report forms, the adverse event, duration of the adverse event, severity, seriousness, action taken (none, dose reduced, treatment stopped, specific treatment), results and causal relationship assessment (e.g., related/not related), date of onset or date of discovered, timing of onset of the adverse event of the test drug, study treatment at the time of event, test drug dose in mg/kg at time of event, duration of test drug therapy, concomitant medications, all these data should be determined and described [2].

Vital signs, other physical findings, and other observations related to safety should be analyzed and presented in a way similar to laboratory variables. The clinical relevance of the results should be discussed in the light of other existing data, including any specific benefits or special precautions required for individual subjects. Information on the primary and secondary pharmacodynamics properties of the drug used may contribute to the safety evaluation for potential adverse effect(s) in humans and should be considered along with the findings of safety studies.

Conclusion

Safety and efficacy of any drug for the treatment of any disease is very important. The research work will be weak by the presence of bias, the overarching assumptions they occasionally made, prejudice, and misinformation, can lead to non-accurate data to the readers, which open the door for the usage of these medications without specialist consultation that leads to adverse drug effects or adverse reactions. In studies a better measures must be developed, and larger samples must be used to identify and improve the safety and efficacy of all investigated drugs, as well as rare and more severe side effects that may be associated with its usage. Because of the risk of bias, an adequately sized, double blind

placebo-controlled trail is needed to confirm the efficacy and safety of tested medications in the treatment of diseases in both genders.

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