Drug trials in developing countries: the need for ethics

Drug trials in developing countries may contribute to a better understanding of the properties of antirheumatic drugs. Before this can be done, however, there is a need for ethical committees to oversee the trials and for effective regulation of drug availability.

In Zaire, a few nonsteroidal anti-inflammatory drugs are available, but disease modifying antirheumatic drugs are generally not available and are therefore scarcely used. While a prescription is legally required, drugs can in fact be obtained over the counter. Patients tend to seek help from traditional practitioners, even while taking modern drugs. Clinical trials on antirheumatic drugs have generally not been carried out in developing countries, since rheumatic diseases were long believed to be of little significance in tropical areas. Until very recently, infectious and parasitic diseases constituted the main health priority in developing countries and consequently most drug trials were related to these diseases.

Information currently obtained from drug trials in developing countries in the field of rheumatic disease is scarce. Most of these trials are of minor importance and simply allow manufacturers to confirm what is already known. There is a danger that the negative results of such trials are interpreted very cautiously, while the positive ones are readily accepted. Drug trials in developing countries are feasible only so long as additional parameters are taken into consideration — such as the relation to nutritional status, cultural condition, climate, and so on. Comparative studies including herbal or other traditional medicines have to be encouraged.

Ethical issues

Paradoxically, it seems that the ethical problems raised by drug trials in developing countries are more complicated than those observed in developed ones. Because of attitudes that arose as a result of colonization, drug trials are looked on suspiciously by patients, administrative authorities, and even by medical authorities. People believe that a new agent should be evaluated in the country where it was discovered. Yet surprisingly the same people tolerate the continuous use of old drugs such as Dipyprone (metamizole sodium), phenylbutazone and oxyphenbutazone.

Dr Mbuyi-Muamba is Professor of Rheumatology at the Faculty of Medicine, University of Kinshasa, P.O. Box 123, Kinshasa XI, Zaire.
Suspicion of new drugs may be exaggerated by both the media and the medical authorities. Misunderstandings arise generally from the lack of official guidelines and ethical rules for drug trials.

Another ethical issue concerning drug trials in developing countries arises from the cost of the trials. Because of the difficult economic situation, the drug manufacturers have to pay all the costs of a trial, including even the transport of patients to the hospital. This financial element may bias the results. There is also the problem of obtaining written consent from patients, most of whom are illiterate and are frightened off by the long list of possible side-effects.

Drug regulation and availability

Although legislation on drug importation may exist, drugs are often imported through obscure and devious ways, which render regulation and price control difficult. Import and handling costs increase the price of drugs. While official pharmaceutical distributors exist, they are unable to meet all pharmaceutical needs and this leads to the development of parallel means of drug importation.

In many developing countries drugs may be prescribed by unqualified persons and self-medication is widespread. A survey conducted in 1988 in Kinshasa showed that 60% of 3043 rheumatic patients diagnosed and treated themselves, 50% sought help from traditional practitioners before consulting western-style health professionals, 40% continued to take both traditional and modern products, and 20% returned to traditional medicine after a short period of western-style medicine.

The most popular analgesic is Dipyrrone, while Aspirin is marketed to a lesser degree. Indometacin is the most popular nonsteroidal anti-inflammatory drug and chloroquine sulfate is the only disease-modifying antirheumatic drug used in Zaire. Corticosteroids (prednisone, prednisolone, cortisone, methylprednisolone and dexamethasone) are commonly used and intra-articular injection is unfortunately often performed by health professionals and often requested by patients.

Traditional drugs include herbal drugs (both local and imported), boa fat and palm nut oil. Herbs may be taken without preparation, or may be cooked or reduced to ash. The ash is generally applied on incisions in the skin. Because of the general belief that rheumatic diseases are caused by an accumulation of "bad blood" in the joints, many patients bear scars from multiple incisions around the joints.

There is a need to have ethical committees not only at government level but also in the institutions where drug trials are being done. This will ensure that the interests of the patients are protected. Much work remains in order to convince the administrative and medical authorities of the value of ethical committees in ensuring optimum conditions for clinical investigations of new drugs.

* * *

As far as rheumatic diseases are concerned, sensibility to pain, morning stiffness and loss of function do not have the same significance in Zaire as in western countries. For example, pain is more accepted in developing countries, and loss of function and deformity in adults may be considered normal signs of aging. The regulation of drug availability is essential, and alternative traditional drugs and techniques merit the attention of trained scientists.