

Role of the Ministry of Public Health in Clinical Research in Lebanon: History, Present Situation, and Plans for the Future



**Rasha HAMRA, PharmD,
MPH, Dr. Health Candidate**
*Director of Health Education &
Public Relations Departments
Ministry of Public Health, Lebanon*

There is currently no law to regulate the clinical trials in Lebanon. Yet, the Pharmacy law number 367 dated 11/8/1994 mentioned indirectly that only teaching hospitals in Lebanon are allowed to conduct clinical research involved with using medications under the article 55.

Accordingly, the ministry further explained this article by a decree number 569/2 dated December 4, 1996, and limited the conduct of clinical research to teaching hospitals or hospitals affiliated with a medical school. Currently, there are 24 teaching hospitals that are classified by the Ministry of Public Health and allowed to conduct clinical research in the country. Most of these hospitals have established their own Institutional Review Boards (IRBs) to ensure ethical compliance of researchers and sponsors in the conduct of clinical trials.

The Lebanese Ministry of Public Health noticed the increase in clinical trials in recent years. This increase may be due to several reasons: the availability of teaching hospitals, the high number of professionals/researchers interested in conducting clinical research, as well as the increasing number of sponsors interested in research

in a developing country like Lebanon. In addition, the lack of regulations on clinical trials makes it easier/more attractive for those sponsors to conduct research in Lebanon. Thus in 2012, the Ministry decided to make few steps towards having a direct role in the ethical and regulatory oversight of clinical trials, while waiting for the issuance of a relevant law by the parliament. The Ministry issued memo number 27, dated April 20, 2012 followed by memo number 72, on September 14, 2012, enforcing the registration of clinical trials in the country. The memos request hospitals, involved in clinical trials, to submit the following documents to the Ministry for each clinical trial: the clinical research protocol, the IRB approval and the principal investigator declaration that the study is done



under his/her direct supervision. This registration is a prerequisite for clinical trials that involve the importation of investigational products and/or the importation and exportation of biological/chemical samples. Furthermore, the Ministry issued a ministerial decree number 2440/2, dated December 27, 2012 to explain how and where the documents should be submitted at the Ministry. Effectively, all the relevant documents should be submitted and officially registered at the Pharmacy Department, where an assigned pharmacist receives the documents for further processing. The submitted documents, especially the study protocols, are handled with confidentiality. In addition, the Ministry of Public Health formed a national committee which is responsible for the regulation of clinical trials in Lebanon through a ministerial decree, number 1398/1 dated August 30, 2012. The latter committee is headed by the Director-General of the Ministry of Public Health and includes, in addition to staff from the Ministry, representatives of the Lebanese University, the Saint Joseph University, the American University of Beirut, and representative of a teaching hospital. The mandate of this committee is to suggest mechanisms for the regulation of clinical trials in Lebanon, including setting guidelines and standards for: conducting clinical trials, formulation of IRBs at teaching hospitals, guidance for ethics review of research proposals, medical and research control audits, patient/participants safety assurance, among other things. All these standards and guidelines will be developed based on international guidelines from WHO, EMEA and FDA. In early 2013, the Ministry of Public Health initiated contact with the ethics and social determinants department

at the World Health Organization headquarter to show the ministry's interest in establishing a clinical trials registry, not only for the country but for the EMRO region as well, since Lebanon can play an innovative role in this regard. The establishment of such a registry in the region will increase the transparency, the comparability, and the quality of clinical trials. The WHO showed willingness to provide technical and logistic support, as well as the training for the clinical trials registration to the staff at the Ministry, and to the interested professionals in the country.

The Ministry of Public Health is presently planning to establish an accreditation system in order to review the existing IRBs in the country, authorize/certify and supervise their work, where only accredited IRBs will be allowed to approve clinical trials, encourage affiliation between accredited IRBs and institutions that do not have an accredited IRB, and organize a national workshop on ethics and clinical trials registration in Lebanon to adopt WHO guidelines regarding standards and operational guidance for ethics review of health related research and international standards for clinical trials registries.

The regulation of clinical trials is a priority for the Ministry of Public Health, since ensuring high standards of patient safety is one of the Ministry's mandates. By setting clear regulations and by standardizing the conduct and quality of clinical trials across Lebanon, the research environment will be improved. This will result in greater benefits to patients, without undue administrative burden on clinicians, researchers and sponsors.

Infos

Aliments pour Garder la Ligne

Pour perdre du poids, un régime n'est pas toujours nécessaire. Il suffit parfois de changer quelques habitudes en misant sur certains aliments...

Les viandes blanches: Riches en protéines et en oligo-éléments, les viandes blanches constituent un allié minceur de poids. Les protéines aident à la formation d'enzymes digestives. Celles-ci ont la faculté d'assurer une sensation durable de satiété.

Plus maigre que la viande rouge, le poulet est par exemple l'une des viandes les moins caloriques, à condition de le consommer sans la peau. Les escalopes de poulet sont également recommandées car elles sont pauvres en lipides (1,5g pour 100g) et en calories (100 kcal pour 100g). Les viandes blanches, ayant un pouvoir antioxydant reconnu, ont l'avantage de pouvoir être consommées de différentes façons: dans des sandwichs, des salades, grillées à la poêle ou parfumées avec des épices, leurs saveurs seront décuplées.