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Modern Homeopathic Proving

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Abstract

The author highlights the analogy between allopathic and homeopathic pharmacology, overviewing of national and international authorities that have developed similar regulations to ensure the quality, efficiency and safety of allopathic and homeopathic medicines. Given the objective considerations which advocates equality between allopathy and homeopathy, it is concluded on the utility of using allopathic experience in the research and development of homeopathic medicines. In this sense, the only way to modernize the practice of homeopathy is practicing the modern proving, folloing the allopathic model. A model of a phase 1 trial protocol for homeopathic proving is presented.

Keywords: proving, trial, homeopathy

Rezumat

Autorul evidentiaza analogia dintre farmacologia alopata si cea homeopata, trece in revista autoritatile nationale si internationale care au elaborat reglementari asemanatoare, pentru asigurarea calitatii, eficientei si sigurantei medicamentelor alopate si homeopate. Tinand seama de considerente obiective care pledeaza pentru egalitatea dintre alopatie si homeopatie, se conchide asupra utilitatii folosirii experientei alopate in cercetarea si dezvoltarea medicamentului homeopat. In acest sens singura modalitate de modernizare a homeopatiei este practicarea provingului modern, dupa modelul alopat. Se prezinta un model al unui protocol al fazei 1 a trialului pentru provingul homeopat.

Cuvinte cheie: proving, studiu clinic, homeopatie

INTRODUCTION

In the author's book, titled " General Homeopathic Pharmacology", now in its third edition, revised and updated[1], some undeniable evidence were put forward, regarding the analogy between the allopathic and the homeopathic medicines, but also between the homeopathic and the allopathic pharmacology.

In his essay *The medicine in this century*[2], the author has shown **that, for a long time already, there are national and international regulations that equate the two types of medicines, allopathic and homeopathic ones**.

In recent years, concerns have emerged for the introduction in the field of the homeopathic drug of more and more aspects from the allopathic drug sphere.

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These include the **establishment of a set of rules for conducting the homeopathic drug proving**, rules that should be consistent with those used for the allopathic medicines.
For one more instance, the author expresses his belief that this is the only way to remove homeopathy from the intolerable situation in which it finds its self, considering the conclusions regarding the reliability of classical pathoegenesis[1(Chapter 12.2.1.4)]

General considerations regarding drug research and their insertion into therapeutics
For those readers that do not have sufficient information on some key issues regarding the drug research and its introduction in the therapeutic use, we appreciate it useful to present the following considerations[4].
Throughout the history and existence of a drug, there are **two main stages**:
- **research,** in order to introduce it into therapeutic practice;
- **use** in therapy.
For all these activities, there are for a long period of time, rigorous national and international regulations, resulted from complex development, at different levels.
The highest international level is the "International Conference on Harmonisation" (ICH)[3], which consists of the European Commission (through EMA), the European Federation of Pharmaceutical Industries and Industry Associations, the Japanese Ministry of Health, the Japanese Pharmaceutical Manufacturers Association, Food and Drug Administration (FDA), Pharmaceutical Research and Manufacturers of America (PhRMA). ICH has formulated guidelines for clinical research for the past ten years and for the criteria regarding the authorization of medicinal products *i.e.* **safety, quality, efficiency**. ICH regulations are applied to all drug records in the EU, USA and Japan. It aims to harmonize research and activity development, in order to ease trade and saving human, animal and material resources.
The European Union, through the European Medicine Agency (EMA), has developed guidelines for good clinical practice (Good Clinical Practice - GCP)[5].
All research performed on humans must comply with the *Declaration of Helsinki*[6].

THE INTRODUCTION OF ALLOPATHIC MEDICINES TO THERAPEUTICS
A preclinical evaluation and clinical one are necessary.
Preclinical evaluation is performed in laboratory animals. Initial **pharmacological screening** is carried out, in order to select potentially active compounds. Molecules that prove of interest are subject to **quantitative testing**. Substances that show prospects pass to **preliminary toxicity tests**. The molecules that pass these tests are taken into research for **pharmacokinetics, pharmacodynamics and toxicology**. B**ased on the formacodynamic effects therapeutic indications are concluded**.
Using the research tools mentioned above, **for about 100 new molecules, only one ends up to be selected for clinical testing**. In order to do this, physicochemical and pharmaceutical research are performed.
Clinical evaluation goes through several stages or phases:
Phase one, refers to **clinical pharmacology**. It is performed on healthy volunteers. It aims to obtain preliminary pharmacokinetic, pharmacodynamic, pharmacotoxicological information.
Phase two, **the first therapeutic trials** are performed on hospitalized patients, based on pharmacodynamic data.
The third phase, extensive therapeutic evaluation is performed on patients admitted and/or outpatients.

The fourth phase, tracking the efficacy and safety, is performed folloing the therapeutic use authorisation.

INTRODUCING HOMEOPATHIC MEDICINES TO THERAPEUTICS

The analogy with allopathic medicines is crucial allowing the bestter knowledge of similarities and differences between the two types of drugs.

Usually, **national and international authorities, in order to authorise and register homeopathic medicines, call for the same documents for approval and registration of homeopathic drugs as for the allopathic ones**, but only with some minor differences.

In order to obtain these documents, homeopathic **medicinal products research presents however differences which are dictated by their particularities**.

Preclinical evaluation is excluded, as all research is made directly on humans.

To reach clinical evolving, until several years ago, **in order to determine the nature of the therapeutic indications, provings were conducted**, following empirical methods[1(Chapter 12.2.1.3)].

Patogenesis were conducted, with worthless, objective scientific value and with a inadmissible reliability[1(Cap12.2.1.4)].

For several years, scientific documents have been developed, only after some homeopaths have understood that **the only correct way to perform homeopathic medicinal product research is to apply the allopathic pharmacology experience**.

Logically, the process started with phase 1. As a specific aspect of homeopathy, it should aim **to assess safety and to provide the pharmacotoxicological spectrum**. This goal is identical to the one of the classical proving.

Based on the symptoms shown in this phase, therapeutic indications shall be specified, for which the assessment is to be made, also using the experience of allopathy for the next phase.

Thus arose the **modern homeopathic proving models**, whose main ideas are presented below.

So far, **homeopathic proving trials** have been published, also called **homeopathic pathogenetic trials**, and were considered to be **clinical phase trials**[1]. These trials is achieved by administering the investigated substances in high dilutions, compared to placebo, using randomized batches and the double-blind procedures.

MODERN HOMEOPATHIC PROVING

The main ideas of a phase 1 trial protocol for homeopathic proving are presented below. They were prepared by Michael Teut *et al.* from the Institute of Social Medicine, Epidemiology and Health Economics of the Charité University Medical Center, Berlin, Germany. The protocol was published on the Internet with permission to be used without restriction[7].

Method

Study project

Phae one trial, placebo controlled, multicentric, randomised, double blind.

Subjects

Medical students and volunteer physicians.

Inclusion criteria

Subjects must be over 18 years old and they should not have been exposed to any treatment for acute or chronic illness on the day of admission. Written informed consent was obtained.

Excusion criteria

Breastfeeding mothers or pregnant women. Persons receiving homeopathic treatment in the previous six months.

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People who have participated in other clinical trials during the past six months. Persons that could be personally or professionally dependent to the physician conducting the study or to the sponsor. Persons placed by the authorities in hospitals or other insititutions.

Researchers
Homeopathic physicians accustomed to homeopathic proving, having at least three years of practical experience in homeopathic therapy. All investigators will have a two days schedule, based on the knowledge of GCP, the Declaration of Helsinki, the national regulations, trial study procedures.

Ethics and consent
All subjects will fill in a written consent, following the prior notification on the ICH guidelines, the Helsinki Declaration, national regulations. Subjects should receive the brochure that was specially inteded for them. The study is approved by an ethics committee.

Procedures
The study is performed in a preliminary period of seven days (basic observations). five days period of intervention follows, then a monitoring period of 16 days. An investigator follows no more than three subjects. After consent, subjects have to be physically examined, then go thorugh a homeopathic interview lasting between 60 and 120 minutes and are instructed on the technical aspects of the trial.
Subjects and investigators should appreciate comments on homeopathic medicines with answers on four levels.

Questions for the subjects
A. "*How do you estimate your sensitivity to homeopathic remedies in general*?". Possible answers: strong reaction / low reaction / no response.
B. "How do you expect to react to homeopathic drugs?" Answers: a very large number of symptoms / many symptoms / no symptoms.

Questions for researchers
A. "*How do you estimate the sensitivity of your subjects to Homeopathic remedies in general*?". Responses: as described above.
B. "*What do you expect in terms of subjects' reactions to homeopathic drugs?*". Responses: as described above.
After the start of the trial, subjects must fill in daily personal charts, mentioning any new or unusual symptoms. Every three days subjects telephone the investigators. The charts should accurately describe the exact locations of the symptoms, sensations, modalities, concurrent symptoms, changes in mental and emotional status. Special attention is given to strange, individual, uncommon or particular symptoms.

Randomising and treatment assignment
Subjects are randomized for interventions and receive a code number that is unique to each subject.

Intervention
Subjects are taking five granules of the studied drug, of 12CH potency, five times a day for no more than five days. Placebo consists of inert granules.

Results parameters
The primary outcome parameter is the number of characteristic proving symptoms per subject.
The secondary outcome parameters are: the total number of proving symptoms, na matter is they are characteristic or not. A comparison is performed considering the qualitative differences in the proving profiles of the characteristic symptoms, between the homeopathic medicine and the placebo.

Estimation of group size

Thirty healthy volunteers are included. A 20% drop-out is accepted. Thus, 24 subjects will be available for analysis.

Analysis

The daily charts are subject to qualitative and quantitative analysis. The qualitative analysis is performed by experienced homeopathic physicians and the quantitative one by statisticians.

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