

**ECH POSITION PAPER:
ARE HOMEOPATHIC PROVINGS COMPARABLE
TO CONVENTIONAL CLINICAL TRIALS?
Version 1, 2005**



1. Definition

In a homeopathic proving, also called proving trial or pathogenetic trial, a homeopathically prepared substance is administered to healthy volunteers in order to produce the symptoms specific to that substance and thereby reveal its inherent curative powers. The effects which occur are documented and systematically arranged to form a symptom pattern or 'remedy picture' which is specific for that particular substance. The Similarity (or Similia) Principle states that substances capable of causing disorder on any level in healthy subjects can be used as medicines to treat similar patterns of disorder experienced by people when they are ill. Recognizing the symptoms of an individual subject and matching them with the symptom pattern from a homeopathic proving is considered to be a key element in the successful practice of homeopathy.

Every single effect and alteration that occurs in the proving (1) provides the basis for the perception of the homeopathic symptom pattern and the better understanding of the possible effects of that particular substance on ill individuals. In homeopathic provings, therefore, any distinction between main/desired effects and unwanted/side effects is totally irrelevant. During the trial, the aim of the homeopathic medication is not to improve a disease or the symptoms of a disease but to provoke symptoms of an artificial illness which is completely reversible after discontinuing the tested substance.

Provings are always conducted at a non-toxic level, i.e. by using substances with a sufficient degree of dilution to guarantee the safety of the medicinal product¹ and are therefore to be distinguished from the investigation of toxicological effects of homeopathic medicines in low potencies or as mother tinctures².

2. History and purpose of homeopathic provings

Homeopathic provings were first conducted in 1790 and described in 1796 by the German physician Samuel Hahnemann. He started experimenting on himself (China, 1796) and gradually extended the testing procedures to a growing group of students, friends and colleagues. Beginning with mother tinctures, later on developing the homeopathic potencies (dilution and succussion), he proved some 100 remedies in the course of his life. As a result of his observations and insights he laid down exact and clear instructions for performing provings in his writings. These regulations are still valid today, but there have been consistent efforts, during the past 20 years, to incorporate contemporary research methods into homeopathic provings. It is the ambition of the ECH to promote the implementation of modern homeopathic provings, based both on traditional homeopathic standards and contemporary research methods, the latter including GCP guidelines for clinical trials. It is a challenging question, if and to what extent a homeopathic proving is comparable to a clinical trial, the purposes of the two being different, but (partially) not the technique.

¹ According to Directive 2001/83/EC the safety of a homeopathic medicinal product is guaranteed if the medicinal product does not contain either more than one part per 10 000 of the mother tincture and more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.

² A risk assessment of toxicological data is especially important for the market authorization of low potencies and mother tinctures.

3. Objectives of homeopathic provings

The basis of homeopathic thought is that health is a dynamic process that tends to maintain a state of optimum equilibrium and that homeopathic medicines induce a process of reorganization of vital functions by stimulating the self-regulatory mechanism. Any substance on earth, from mineral, botanical, or zoological origin, is considered to be potentially medically useful. Provings are essential to reveal the inherent curative powers of these substances. In fact, this is their first and foremost aim. A comprehensive list of all these proved experiences is laid down in the homeopathic materia medica.

A main objective of homeopathic provings is the enhancement of materia medica and, along with it, of therapeutic options for homeopathic treatment, i.e. the creation of new symptom patterns or ‘remedy pictures’, or the amplification of already existing symptom patterns.

Due to the current requirements by the authorities of many EU Member States the existence of significant homeopathic provings alongside pharmacological data (origin, production, identity, toxicity etc) is important for the registration and market authorization of homeopathic medicinal products.

The second important objective of homeopathic provings is to facilitate the registration and market authorization as a medicinal product by the authorities of EU Member States.

It is possible today to come to statistic statements and inter-individual comparisons by using modern scientific tools. This enables us to come to conclusions about the quality of homeopathic provings and about the proving methodology in general. Provings can also contribute to the evidence base of homeopathy. After all, if the effects of homeopathic medicines in provings can without any doubt and repeatedly be attributed to the homeopathic medicine used and not to placebo (blank), this is evidence for the efficacy of the tested medicine and thus for the efficacy of homeopathy in general. This is a very important element in present-day political discussions about the acceptance or otherwise of complementary/unconventional therapeutic methods into the social security systems.

The third important objective of homeopathic provings today is their contribution to the evidence profile of homeopathy.

4. Management of homeopathic provings

- a. A proving is basically a prospective study. Matter, goal, plan, management, analysis, protocol and design are fixed in advance according to scientific standards.
- b. Next Step: selection of subjects. Size of the group (10-50 provers), age allocation, sex allocation, proving experience are identified and fixed. There is a catalogue with clearly defined exclusion criteria, which serves for the final formation of the group (pregnancy and nursing, severe chronic disease, acute diseases, regular medication, major life changes, etc.). The more proving experience, the better the subject. Every subject signs an Informed Consent Form according to the principles of ICH-GCP guidelines.
- c. Proving medication: Clear-cut data concerning origin, preparation procedure, manufacturer, pharmacology, toxicity (in Germany BfArM, Commission D) are required.
- d. According to GCP guidelines a proving protocol has to be approved by an ethics committee. In order to facilitate the ongoing process of provings it would be appropriate if an ethics committee agreed on a standard proving protocol applicable in each Member State.
- e. The protocol has to be finalised before the beginning of the proving. It contains all data concerning duration, documentation, intake regime, attrition criteria, etc.
- f. The proving director as well as the supervisors have to fulfil predefined criteria concerning qualification and aptitude (theoretical and practical knowledge of provings).

- g. The provers' state of health is investigated before the start of the proving (both a routine medical evaluation and homeopathic case-taking) and documented.
- h. Potency, dosage, duration of administration and attrition criteria are determined as well as the maximally desirable dosage and duration of administration. As a matter of principle, the proving substance is administered until the subject develops clear symptoms.
- i. In modern proving designs the following tools are used: pre-proving observation, placebo control (possibly symmetrical), randomisation, double blinding, run-in phase, post-proving observation, cross-over in bi-phasic design.
- j. Subjects note symptoms in their journals for the duration of the homeopathic proving and are in regular, if possible daily, contact with the proving director or supervisor. Unstructured journals for freely formulated entries can be used as well as diagrammed journals for entries according to head-to-foot scheme.
- k. All symptoms that occur in connection with the proving have to be recorded. Acute intercurrent diseases or strong disturbing external factors lead to exclusion of the prover. This has to be recorded in the journal. Reporting paths in case of severe proving symptoms are delineated.
- l. Evaluation of journals, decoding and biometrics, assessment of the results and publication are accomplished according to given scientific standards. Verum as well as placebo (blank) symptoms are separately recorded after decoding and compared.
- m. The subjects are not supposed to have personal contacts during the proving until decoding. Beginning and end can vary between subjects.

5. Differences between homeopathic provings and conventional clinical trials

The clinical testing of experimental drugs is normally done in four phases, each successive phase involving a larger number of people. Phase I studies are primarily concerned with assessing the drug's safety and designed to determine the pharmacodynamics of the drug – how it is absorbed, metabolized, and excreted. This initial phase of testing in humans is done in a small number of healthy volunteers (20 to 100). Phase II is a clinical efficacy test with a larger number of subjects (100-200). By previously conducted pharmacological tests the indication spectrum of a medicament has been experimentally identified. Apart from the curative properties for defined medical conditions (high blood pressure, migraine, headache, etc.) unwanted side-effects – which can be unpleasant, serious or even life-threatening – and drug tolerance are to be assessed. Phase III studies are also trials with patients regarding effects and side-effects as well in the hospital as with practitioners. Phase IV studies, or post-marketing surveillance studies, are conducted after the first registration.

In their practical aspects several similarities can be observed between homeopathic provings and conventional clinical trials. In either set-up medication is administered to a small number of healthy volunteers and its effects are accurately observed and documented. Both use non-medicinal substances as control. Both lead to conclusions regarding the effects of the administered medication. However, conventional clinical trials are aimed at assessing the efficacy of a drug in specific medical conditions and its side-effects (in phase II), whereas homeopathic provings are **not** used for testing the efficacy of a medicine in a specific medical condition and are **never** conducted on **patients**. The only purpose of provings is to identify and document all emerging effects and symptoms, leading to a 'remedy picture' generated from the totality of observed symptoms, which can serve as a matrix to be compared with the totality of the symptoms of a diseased patient. This aim might be described as searching for side-effects without a main indication.

Not only does the purpose of provings differ from that of conventional clinical trials, neither do provings follow the four-phase set-up of conventional clinical trials. Although, as said above, there are several technical similarities, provings may only be considered as a **homeopathic version of a clinical trial phase I**, not as identical with a clinical trial phase I. If after several provings no more new symptoms arise, the objective of a complete 'remedy picture' will have been achieved. Phase II – IV studies in homeopathic trials are unnecessary, as provings are always conducted at a non-toxic level, which means there is no risk of side-effects or toxicological effects.

6. Conclusions

Although there are several technical similarities between homeopathic provings and conventional clinical trials, provings may only be considered as a **homeopathic version** of a clinical trial phase I, which means rather similar but not identical with a clinical trial phase I. The purpose of homeopathic provings vs. conventional clinical trials is clearly different. Homeopathic provings are **not** used for testing the efficacy of any treatment in specific medical conditions, are always conducted on healthy volunteers and **never** on **patients**. Their only purpose is to identify and document all emerging effects and symptoms at a non-toxic level.

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The European Committee for Homeopathy or ECH is the European association for all statutorily regulated health professionals (medical doctors, veterinarians, dentists, pharmacists, midwives, etc.) in the field of homeopathy, as well as other professionals who can contribute to the development of homeopathy. To date 33 homeopathic doctors' associations in 23 European countries are affiliated to the ECH.

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