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## A systematic review on methodological qualitative Homoeopathic Pathogenetic trials and modern clinical trials

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### Abstract

Hahnemann father of experimental pharmacology through his continuous efforts discovered unique method drug proving through many innovative methods. Guidelines had been clearly explained in Organon which is source knowledge of Homoeopathy. But there is continuous criticism about the methodology of HPT'S, reliability and validity of symptoms through drug proving. A modern clinical trial focuses more on methodology of trials to reduce bias and the same is followed by HPT'S.

**Methodology:** An intense literature search was made using electronic data bases, hand searching, journals, web pages, reviewing bibliography resources, available publications

**Keywords:** HPT'S, clinical trial, prptocol, phase Itrials

### Introduction

One of unique method of Homoeopathy is Drug proving. it is an instrument to know the pathogenesis of a drug in different individuals who are apparently healthy. Hahnemann conducted repeated experiment on him and healthy volunteers and established new proving technique which is called as drug proving. First proving is done in Homoeopathy is by Master Hahnemann in 1970 of drug Cinchona officinalis. He proved on himself and elicited the pathogenesis of drug through which drug picture of Cinchona had evolved.

Hahnemann also called as father of experimental pharmacology and laid new foundation of drug proving by proving on him. He proved 99 drugs on himself, family, friends, Colleagues. In his book Organon of medicine under 105-145 aphorism he explained clearly methods to conduct drug proving and instruction to be followed. Drug Proving was formally initiated by the Homoeopathic Research Committee (formed in 1963). Since inception of the CCRH, the proving program has been continuing and is one of the most important research programs of the Council. Clinical trials are performed to make life better for people who are living with chronic diseases or life threatening diseases.

The Nuremberg trials in 1946 brought the issue of inhuman treatment of some individuals included in 'research' to the attention of the public. The World Medical Association (WMA) published its first version of the Declaration of Helsinki in 1964, which has been revised several times since (last revision 2013). The first revision of the declaration in 1975 stated that protocols for clinical research should be sent to a 'specially appointed committee for consideration, comment and guidance'. However, under the Declaration of Helsinki, the ultimate duty to ensure the protection of human participants remains with doctors. Clinical trials should be carried out according to the GCP guidelines developed by the ICH. Regulatory authorities in a number of countries require adherence to these guidelines. Thus, any country that adopts the ICH-GCP guideline technically follows the same standards when conducting clinical trials. The ICH-GCP is relevant for ethics since they refer to the principles of the Declaration of Helsinki and include guidance on various ethics-related processes and procedures. This includes ethics evaluation, investigator qualification, consent and confidentiality. In most countries, there are regulations or guidelines that apply to any type of research involving humans.

### Need of study

There is a great need of study to create an impact on individuals that Homeopathic drug proving is done as per clinical trial protocol which follows GCP guidelines.

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It is need of hour to know that drug proving in homoeopathy is not of low methodological quality but follows all guidelines as per new clinical trial design.

### Objectives

To know the flaws in drug proving during Hahnemannian time. To establish a truth that HPT are done according to modern clinical protocol. To understand where HPT differs from clinical trial.

### Methodology

#### Materials and Methods

An intense literature search was made using electronic data bases, hand searching, journals, web pages, reviewing bibliography resources, available publications, Major scientific databases namely PubMed, Science Direct and Springer were searched. The search words used were drug proving, clinical trial, phases of clinical trials, HPT, CCRH.

#### Study selection

All titles, abstracts and complete articles were independently reviewed to eliminate duplications.

#### Inclusion criteria

Publications of English language are used, press note.

#### Exclusion criteria

Unpublished data such as dissertations were not included.

#### Data extraction

The database search was carried out to find relevant scientific papers published up.

It revealed that different clinical trials are going on in different areas. There are many phases of clinical trials conducted by principal investigator. HPT is also done in different potencies in different individuals in different places of research centers.

### Discussion

A review published in 2007 revealed that most of drug proving conducted between 1945-1995 were not having high methodological quality. Absence of Study designs, absence of control groups, absence of random allocation, absence of blinding, inclusion of trival and preexisting symptoms are not involved in study are some of the flaws during Hahnemannian proving. Most of the provers are repeated due to which chances of bias is more. Most of old studies were conducted to know clinical conditions, thereuptic properties of drug. In an article Dantas explored on flaws on drug proving. But recent researchers and Homoeopaths have developed standard protocols to conduct homoeopathic pathogenetic trials. Now – a day's most of researches is focused on experimental designs, control groups, identification of new symptoms for thereuptic purposes. A recent research explored that since last 20 yrs systemic review of 147 HPT'S on 214 drugs has been published. It emphasis that lot of research on drugs are going on with developed tools. Most of the researches believe that methodology which is adopted previously should change rather than priority of thereuptic indication of drugs.

Modern clinical trials have four phases. phase 1 trials are done on small group to identify safety, side effects and correct dosage of drugs. Phase 2 lays most emphasis on

effectiveness of drug on more individuals, phase 3 on drug safety and effectiveness of it in different doses and on individuals, phase 4 in large group of individuals in different doses. HPT'S trials are more co related with phase 1 trial in terms of sample size, trial design like randomization, single blind, double blind, control groups, cross sectional studies. Phase 1 focus more drug safety, bio availability of drugs following GCP guidelines but HPT'S focus on pharmacodynamics of drugs, to know the disease curing power of drugs by following the updated guidelines and protocols adopted by CCRH as per GCP guidelines. eligibility criteria, inclusion and exclusion criteria is almost same in all proving protocol of HPT'S but in clinical trials it differs based on drug. the data obtained through HPT'S is thoroughly analyzed, compiled and thus Homoeopathic Materia Medica is obtained.

### Conclusion

HPT'S are now having high methodological quality. Chances of bias are very less. Results of HPT'S are very relevant and can further used for comparison with other homoeopathic drugs. Healthy prover safety is always protected through updated protocol.

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### Author's Contribution

Not available

### Conflict of Interest

Not available

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