Clinical Trials of Traditional Herbal Medicines In India

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Introduction

• Use of traditional medicines (TM) remains widespread in developing countries like India
• Use of complementary and alternative medicine (CAM) is increasing rapidly in developed countries For the use of large animals, permission to be obtained from Chennai office.
What includes Traditional Medicines?

Diversity of health practices, approaches, knowledge, and beliefs incorporating plant, animal, and/or mineral-based medicines; spiritual therapies; manual techniques; and exercises, applied singly or in combination maintain well-being, as well as to treat, diagnose, or prevent illness

…..WHO
Potential Risks

- Direct risks of adverse effects and drug interactions
- Indirect risk that traditional remedies without demonstrated efficacy may compromise, delay or replace an effective form of conventional treatment.
Risks....

- Hazardous in specific patients under special circumstances or when combined with conventional drugs.
Categories of Herbal Drugs

• The substance is being clinically evaluated for same indication for which it is being used or as has been described in the texts.

• b. An extract of a plant or a compound isolated from the plant has to be clinically evaluated for a therapeutic effect not originally described in the texts of traditional systems- new chemical entity (NCE)

• Never been in use before and has not ever been mentioned in ancient literature.
Concerns about Clinical Study Designs

- Methodological quality is variable
- Quality of the trial drug has to be tested for batch-to-batch uniformity of the active constituents
- Source, processing, and final composition of the herbal product
- Herbal trials generally use placebo and not an active comparator
Concerns about Clinical Study Designs….

- Study should be adequately powered.
- Combined use of an herbal medication and a conventional drug considered in clinical trials
- Adequate doses of both herbal drug and active comparator to be used
Benchmarks Of A Clinical Trial Using Herbal/Traditional Medicines

• If Design of the trial is appropriate to provide the expected outcomes for the traditional medicine.

• Whether the methodology limits the treatment procedure of traditional medicine.
In order to avoid the loss or alteration of the efficacy of the substance, validated methods needed while adapting modern method to formulate and dispense the medicaments.
Challenges

- Regulatory Status
- Assessment of safety
- Efficacy
- Quality Control
Regulatory Requirements For The Conduct Of Clinical Trials on Herbal Medicines

- Traditional medicines are governed by the Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945.

- In 1959, the Government of India amended the Drugs and Cosmetics Act to include drugs which are derived from traditional Indian medicine.
Regulatory Requirements…..

• In 1993, the guidelines for the safety and efficacy of herbal medicines developed by an expert committee.
• No new herbal medicines other than those authorized by the licensing authorities be allowed to be manufactured or marketed, except for those mentioned in ancient scriptures.
The procedures laid down by the office of the DCGI for allopathic drugs should be followed for all traditional and herbal products to enter into clinical trials for any therapeutic condition.
Co-investigators/collaborators of the expert group are from the associations of physicians from the concerned system for designing and evaluating the Study.
Phases of Clinical Trials

- Phase I studies may not be necessary
- Need for testing its toxicity in animals has been considerably reduced.
- Toxicity study may not be needed for phase II trial unless reports suggesting toxicity/herbal preparation is to be used for more than 3 months
Phases of Clinical Trials…

- Larger multicentric phase III trial is subsequently planned based on results of phase II study.
- These trials have also got to be approved by the appropriate scientific and ethical committees of the concerned Institutes.
Challenges which need to be addressed

- Quality control of herbal medicines is complicated and difficult
- Relevant appropriate requirements should be established for the assessment of safety and efficacy for different categorized herbal medicines to reduce cost and expenditure
- Integration of traditional medicine into national health systems