

Clinical Studies

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Plants produce primary and secondary metabolites which have been exploited by humans for many different beneficial purposes. Many secondary plant metabolites, e.g. terpenes, terpenoids, alkaloids and phenolic compounds have been well characterized. Essential oils are considered the chemical weapons of plants, as their compounds may deter insects or protect plants against bacterial and fungal infections. They also act as plant pheromones to attract insects. In traditional medicine, lots of plant products have been widely used for the treatment of neurologic diseases, cancer, inflammation and infectious diseases and plants represent an abundant source of new bioactive secondary metabolites.

According to the Communicable Diseases Centre in the US, about one third of prescribed antibiotics were inappropriate thus stating an overuse and misuse of antibiotics. Essential oils are also highly active against multi-resistant *Staphylococcus aureus* (MRSA), one of the so-called hospital super bugs, as well as more common and wellknown infections like herpes labialis. In addition to antibacterial and antiviral effects, essential oils have been shown to possess many useful pharmacological properties, often being more effective than conventional drugs and revealing fewer side effects. Although the number of published papers on anti-infective properties of medicinal plants is increasing during the last years, most of these papers seem to somehow disappear and do not attract physicians and pharmacologists. On the other side, there is often lack of finance to continue research to the clinical trial level. This area is usually largely dominated by pharmaceutical companies who can afford costly clinical trials. It also seems that natural and complementary therapies are pushed aside by pharmaceutical companies. Although there is no shortage on research about anti-microbial effects of medicinal and aromatic plants, it is somehow ignored in industrialised countries. Prescribed drugs are more convenient for patients and physicians, although natural products might offer an alternative in treatment of many different diseases. In resource limited countries, conventional medications are often not affordable or not available and consequently natural products are the medication of choice.

Clinical trials are experiments done in clinical research. Such prospective biomedical or behavioral research studies on human participants are designed to answer specific questions about biomedical or behavioral interventions, including new treatments (such as novel vaccines, drugs, dietary choices, dietary supplements, and medical devices) and known interventions that warrant further study and comparison. Clinical trials generate data on safety and efficacy.[1] They are conducted only after they have received health authority/ethics committee approval in the country where approval of the therapy is sought. These authorities are responsible for vetting the risk/benefit ratio of the trial - their approval does not mean that the therapy is 'safe' or effective, only that the trial may be conducted.

Depending on product type and development stage, investigators initially enroll volunteers and/or patients into small pilot studies, and subsequently conduct progressively larger scale comparative studies. Clinical trials can vary in size and cost, and they can involve a single research center or multiple centers, in one country or in multiple countries. Clinical study design aims to ensure the scientific validity and reproducibility of the results.

The first proper clinical trial was conducted by the physician James Lind.[12] The disease scurvy, now known to be caused by a Vitamin C deficiency, would often have terrible effects on the welfare of the crew of long distance voyages. In 1740, the catastrophic result of Anson's circumnavigation attracted much attention in Europe; out of 1900 men, 1400 had died, most of them allegedly from having contracted scurvy.[13] John Woodall, an English military surgeon of the British East India Company, had recommended the consumption of citrus fruit (it has an antiscorbutic effect) from the 17th century, but their use did not become widespread.

Lind conducted the first systematic clinical trial in 1747. He included a dietary supplement of an acidic quality in the experiment after two months at sea, when the ship was already afflicted with scurvy. He divided twelve scorbutic sailors into six groups of two. They all received the same diet but, in addition, group one was given a quart of cider daily, group two twenty-five drops of elixir of vitriol (sulfuric acid), group three six spoonfuls of vinegar, group four half a pint of seawater, group five received two oranges and one lemon, and the last group a spicy paste plus a drink of barley water. The treatment of group five stopped after six days when they ran out of fruit, but by that time one sailor was fit for duty while the other had almost recovered. Apart from that, only group one also showed some effect of its treatment.

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