

Clinical Trial

A clinical trial is an experiment designed to test the value of a medication, test new types of therapy, find uses for existing therapies or test a medical device for use in human subjects.

Phase I= To define the maximum tolerated dose

Usually done in a small number of patients (<50) at a few centres

Dose is progressively escalated (if tolerated) in groups of around 3 patients

Phase II= To assess the efficacy of a drug for a specific indication

Done in a large number of patients in a number of centres

Phase III=To compare a new drug/treatment with a standard drug/treatment to assess whether it is as effective.

Done in a large number of patients in a large number of centres

Phase IV=To continue collection of safety and efficacy data even after drug is approved for marketing and use

Done in a large number of patients in a large number of centres