

Single ascending dose (Phase Ia)

In single ascending dose studies, small groups of subjects are given a single dose of the drug while they are observed and tested for a period of time to confirm safety.

Typically, a small number of participants, usually three, are entered sequentially at a particular dose.

If they do not exhibit any adverse side effects, and the pharmacokinetic data are roughly in line with predicted safe values, the dose is escalated, and a new group of subjects is then given a higher dose. If unacceptable toxicity is observed in any of the three participants, an additional number of participants, usually three, are treated at the same dose.

This is continued until pre-calculated pharmacokinetic safety levels are reached, or intolerable side effects start showing up (at which point the drug is said to have reached the maximum tolerated dose (MTD)). If an additional unacceptable toxicity is observed, then the dose escalation is terminated and that dose, or perhaps the previous dose, is declared to be the maximally tolerated dose. This particular design assumes that the maximally tolerated dose occurs when approximately one-third of the participants experience unacceptable toxicity. Variations of this design exist, but most are similar.

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