

A rigorous and monitored experimental study* that includes healthy or ill human subjects and that is aimed at evaluating the outcomes of one or more prophylactic or therapeutic interventions.

Note: Each trial is designed to answer specific scientific questions.

- In experimental studies (trials), exposure to a drug or to a therapeutic or preventive manoeuvre is imposed by the investigator. The investigator decides, through some method, including random selection, who will be exposed; in observational studies, whether there is exposure is determined by the subject himself/herself or naturally.

Note: The difference between a trial and a study is quite fuzzy, but they can be distinguished as follows: a trial bears on an intervention that will change the course of things and that applies to humans, while a study examines the outcomes of an intervention or of exposure to a given factor, or may have other aims, such as observing the course of a disease. A trial may be part of a study, but the reverse is not true.