Clinical trials

Clinical trials are prospective research studies conducted with people to assess the safety and effectiveness of new medical treatments, surgical procedures, or behavioral interventions to determine their suitability for general use.

Phases

Clinical trials are typically conducted in four phases:

- *Phase I*. Tests the safety, side-effects and best dose of a treatment for the first time in a small group of participants
- *Phase II*. Determines the effectiveness and safety of the treatment in a larger group of participants, usually up to a few hundred
- *Phase III*. Confirms the efficacy of a treatment in a larger population by comparing it with current standard treatments or placebo and identifies the incidence of adverse effects
- *Phase IV*. Ongoing study after approval that monitors the long-term effects of a treatment in the general population

Study protocol

The protocol is a detailed document that outlines the background, specifies the primary and secondary objectives, and describes the design and organization of the trial.

Personal, financial or professional conflicts of interest that could potentially influence the outcome of the trial must be declared.

There is an ethical imperative to report results of all clinical trials, regardless of the findings, to ensure the advance of scientific knowledge.

Planning and design

- *Randomization*. Participants are randomly assigned to study groups according to an appropriate randomization procedure
- *Blinding*. Participants, health providers and/or investigators are kept unaware of which treatment group participants have been assigned to
- *Control group*. A group of participants against which the intervention group is compared

Data management and analysis

Accurate data collection and robust statistical analyses are essential for assessing the effectiveness of a treatment and for guiding further decision-making.

Registration and ethics

- The International Committee of Medical Journal Editors (ICMJE) requires prospective registration to publish results from clinical trials in medical journals
- Ethical review and approval must be obtained before a study starts

Further information

ClinicalTrials.gov (a place to learn about clinical studies from around the world) https://clinicaltrials.gov/

ClinicalTrials.gov. Clinical trial reporting requirements https://clinicaltrials.gov/policy/reporting-requirements

EQUATOR Network. Database for reporting guidelines https://www.equator-network.org/

International Committee of Medical Journal Editors. Clinical trials https://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html