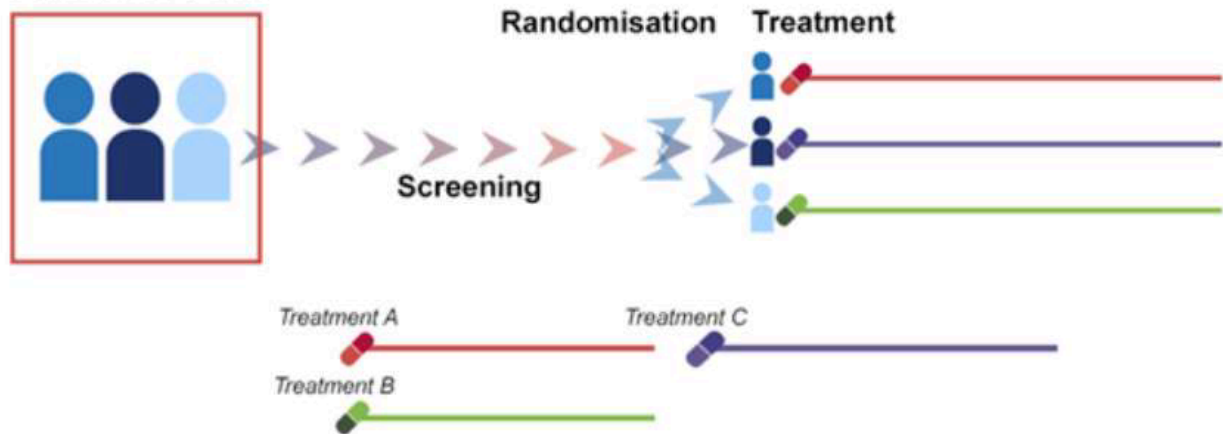
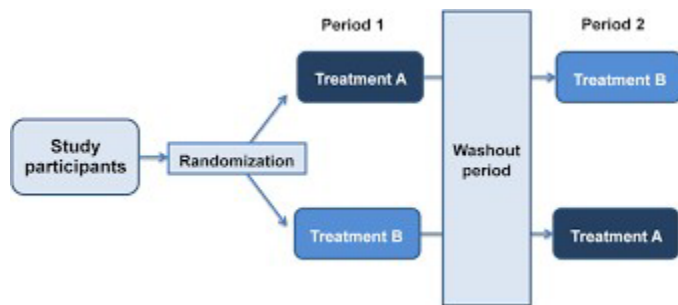


Parallel Trial



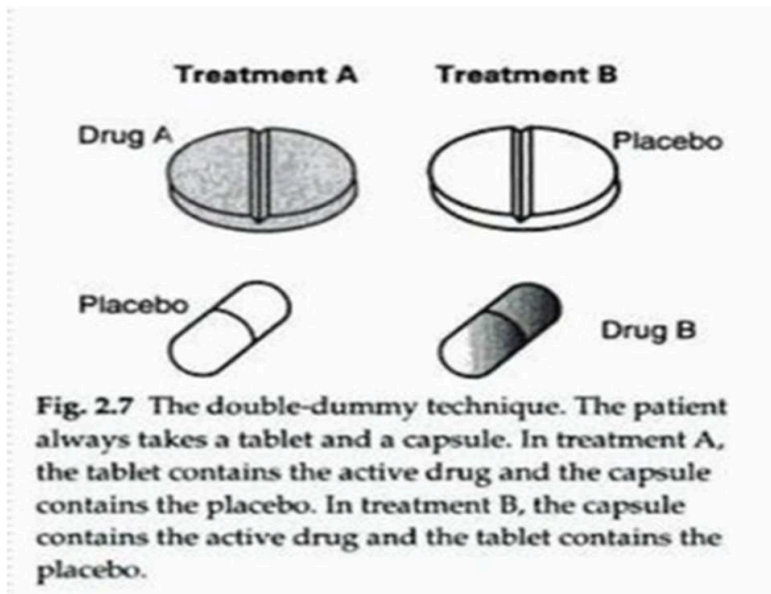
Parallel Design : A randomized controlled trial with a parallel design randomly assigns participants to different groups and each group gets only one treatment or intervention for the whole study



Cross Over Design: A Randomized Controlled Trial with a crossover design is a study where each participant receives two or more different treatments or interventions, but in a random order, one after the

other with a washout period in between to eliminate the effects of the first treatment. A washout period is a planned break between two treatment phases when no treatment is given. Main purpose of washout period is to let the effects of the first treatment wear off before starting the second, so the second treatment's results aren't influenced by the first

Double Dummy Approach:



It is a method used to maintain blinding when comparing two treatments that cannot be made to look identical. This technique ensures that neither the participants nor the researchers know which treatment the participant is receiving, thus minimizing bias.

In the given **example**, one group will receive Treatment A and the placebo of Treatment B; the other group will receive Treatment B and the placebo of Treatment A

Reference Guidelines:

NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS dated 2017:

[ICMR_National_Ethical_Guidelines.pdf](#)

THE NEW DRUGS AND CLINICAL TRIALS RULES, 2019: As amended vide GSR 778(E) dated 14-10-2022, w.e.f. 14-10-2022 : [Circulars](#)

ICH HARMONISED GUIDELINE – GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R3) dated 06 Jan 2025: ICH Official web site : [ICH](#)

Recent Industrial Development(s):

The new ICH GCP R3 guidelines released on 6th January 2025, focus on making clinical trial design more flexible, efficient and patient centered while maintaining high ethical and scientific standards. The guideline Includes the language to facilitate innovations in clinical trial design, technology and operational approaches. The Emphasis of the guidelines is on:

- **Quality by Design (QbD)**, which means planning the trial carefully from the start to ensure safety and reliable results
- **Adoption of a risk-based**, proportionate approach, focusing resources on the most important parts of the trial that affect quality and safety -
- **Fit-for-purpose approach**

For more information, please refer to the guidelines using below link: ICH Official web site : [ICH](#)