

Chapter 5

Clinical Trial

A *randomized clinical trial* is a prospective experiment to compare one or more interventions against a control group in order to determine the effectiveness of the interventions.

A clinical trial may compare

- ✓ The value of a drug versus a placebo
- ✓ A new therapy with a currently standard therapy
- ✓ Surgical with medical intervention
- ✓ Two methods of psychotherapy

NB: A placebo is an inert substance that looks like the drug being tested

5.1 Features of Randomized Clinical Trials

The most important features of randomized clinical trials are:

1. There is a group of patients who are designated study patients. All criteria must be set forth and met before a potential candidate can be considered eligible for the study. Any exclusions must be specified prior to starting the study.
2. Eligible patients are randomly assigned to the experimental or control group.
3. Clinical trial may be blinding (single blind or double blind)

Single blind: patient does not know getting which treatment group.

Double blind: in which neither the treating physician nor the patient knows whether the patient is getting the experimental treatment or the placebo.

4. While clinical trials often compare a drug or treatment with placebo, they may also compare two treatments with each other.

5.2 Purpose of Randomization

- ☞ To produce groups that are comparable (i.e., balanced) with respect to known or unknown risk factors (i.e., prognostic baseline characteristics that could confound an observed association).
- ☞ To remove bias (selection bias and accidental bias).
- ☞ To guarantee the validity of statistical tests.
- ☞ To balance treatment groups, stratification factors, or both.

When to randomize?

- ✓ After determining eligibility.
- ✓ As close to treatment time as possible (to avoid death or withdrawal before treatment start).

5.3 Randomized Assignment

Random assignment into an experimental group or a control group means that each eligible individual has an equal chance of being in each of the two groups. This is often accomplished by the use of random number tables.

5.4 Clinical Trial as “Gold Standard”

Sometimes observational study evidence can lead to misleading conclusions about the efficacy or safety of a treatment, only to be overturned by clinical trials evidence, with enormous public health implications. Because, clinical trial use the technique of **randomization, placebo group and blinding**.