Single-arm trial

The simplest trial design is a single-arm trial. In this design, a sample of individuals with the targeted medical condition is given the experimental therapy and then followed over time to observe their response. This design is employed when the objective of the trial is to obtain preliminary evidence of the efficacy of the treatment and to collect additional safety data but is not generally used as confirmation of efficacy. The design may be desirable when the available patient pool is limited and thus it is not optimal to randomize many participants to a control arm.

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Last update: 2024/06/07 02:55

