

Correspondence address:

Mun Seng Lee
School of Medicine
Universiti Malaysia Sabah
Beg Berkunci No. 2073
88999 Kota Kinabalu
Sabah
MALAYSIA
Email:
seanlee@ums.edu.my

**EDITOR'S
VOICE**

Introduction To Randomised Controlled Trial

Lee MS
School of Medicine, Universiti Malaysia Sabah, Malaysia.

Randomised Controlled Trial (RCT) its aim is to evaluate the safety and efficacy of a new intervention such as new eye drops, new surgical procedures or new healthcare delivery method. The intervention must be conducted randomly. There are 4 phases of RCT; phase 1 concerns of "Safety", phase 2 is "Efficacy", phase 3 is "Randomised Controlled Study" and phase 4 is "Post Marketing". In phase 1, the aim is to get the best dose of drug but it is not randomised. In phase 2, it is to produce preliminary evidence of efficacy and evaluate its side effects but it is also not randomised. In phase 3, it is to discover the efficacy of new treatment and compare it to the control and it is randomised. Finally, phase 4 is to seek uncommon side effect in the market.

Study population selection is to maximise the rate of follow up, maximise the outcome and target a particular group. However, you need to exclude those may develop adverse reaction to intervention, those may be susceptible to unacceptable risk of taking on placebo, those are not at risk, those are likely not responsive to treatment because of terminal stage and those are not compliance. Randomisation is defined as "a selection or assignment process in which there is associated with every legitimate outcome a known probability". This will prevent the patient passing on his task to the next patient thus provide a baseline comparison with the study groups. The intervention should be standardised and stabilised throughout the trial, the side effects should be minimised, the route of administration should be easy and it has the real-life practicality.

Group assignment is very important. Trial group should receive the new medication or intervention, the control group should be granted either standard medication, placebo or no treatment as according to the nature of the trial. Standard procedure or no procedure should be considered in the control group if your choice for trial is intervention. You must define your end point such as visual improvement, prolong disease progression, it affects the baseline or gets more toxic.

One of the advantages of RCT is you may invent a new "Gold standard"; you are confident with your results as comparing with others. RCT is much faster and economical, its influential power to peer is stronger. However, it may be difficult to be incorporated into your daily practice, it creates an ethical barrier, your outcome may be similar to others or inconclusive, it may enhance masking by the subject itself, investigator and data analysis and RCT is subjected to confounder. Confounder is an independent variable that is related to the intervention. Randomisation may minimise its effect, but it will not eliminate it completely. Confounder should be identified prior to the trial, exclusion criteria may help.

In RCT, you need to look out for bias. Bias is a systemic error, it has 4 types: selection, performance, attrition and detection. Bias can be prevented by randomisation, allocational concealment, centralisation, forming your own number for each patient, blinding – preferably double, a good staff communication and establishing a new protocol with everyone's full compliance. This article is an introduction, if you want to conduct a RCT, we suggest you to explore it further.