Randomised controlled trials (RCT’s) are regarded as the gold standard in medical research to prove whether presumed effects of medicinal or other treatments are of a causal nature. There may however be financial, practical or ethical issues which make it undesirable or impossible to carry out an RCT for each and every relevant treatment. As a result, observational research has become a much-used alternative method to estimate the effects and adverse effects of, especially, drugs. This has been partly inspired by the ever growing availability of large quantities of data. From the point of view of the philosophy of science, observational research should only be used to generate hypotheses. Hence, in evaluating findings that are being presented, one always needs to be aware of methodological limitations such as ‘confounding by indication’, the ‘healthy cohort effect’ and the ‘immortal time bias’. One will always have to consider whether it is possible to correct sufficiently for these issues to enable the findings of observational studies to be regarded as valid in terms of establishing a causal effect or association.

**Ge-Bu Indication**

- Randomised double-blind trials are regarded as the gold standard in estimating a causal effect of a drug.
- Randomised research is not possible for all research questions regarding the effect of therapies; it is therefore relevant to consider if, and under what conditions, observational research may be a valid alternative.
- The main scientific objection to using observational studies to estimate a causal effect of a therapy is that the groups to be compared often differ. It is often not possible to adequately correct for these differences, leading to a biased result.
- For some research questions, the risk of confounding is limited, and in these cases observational research can be a good alternative to randomised research; this is particularly true for research into rare adverse effects of drugs. It is also relevant since the follow-up in randomised studies is often too short, and they include too few participants, to be able to detect rare adverse effects.

**Literature references**


