Biosimilars for the Treatment of Cancer: A Systematic Review of Published Evidence

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Supplementary Table S4. Modified Downs and Black Checklist.¹

Quality scoring for randomized and non-randomized studies from conference proceedings will be assessed using the modified Downs and Black checklist.

Reporting			
1.	Is the hypothesis/aim/objective of the study clearly described?	Yes = 1; No = 0	
2.	Are the interventions of interest clearly described?	Yes = 1; No = 0	
	Treatments and placebo (where relevant) that are to be compared should be clearly described.		
3.	Are the main findings of the study clearly described?	Yes = 1; No = 0	
	Simple outcome data (including denominators and numerators) should be reported for all major findings so that		
	the reader can check the major analyses and conclusions. (This question does not cover statistical tests which		
	are considered below).		
4.	Does the study provide estimates of the random variability in the data for the main outcomes?	Yes = 1; No = 0	
	In non-normally distributed data, the inter-quartile range of results should be reported. In normally distributed		
	data, the standard error, standard deviation, or confidence intervals should be reported. If the distribution of the		
	data is not described, it must be assumed that the estimates used were appropriate and the question should be		
	answered yes.		
E	External validity		
All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalized to the population from which the study subjects were derived.			
5.	Were the subjects asked to participate in the study representative of the entire population from which	Yes = 1; No = 0;	
	they were recruited?	Unable to determine = 0	
	The study must identify the source population for patients and describe how the patients were selected. Patients		
	would be representative if they comprised the entire source population, an unselected sample of consecutive		
	patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant		
	population exists. Where a study does not report the proportion of the source population from which the patients		
	are derived, the question should be answered as "unable to determine."		
Internal validity - bias			
6.	Was an attempt made to blind study subjects to the intervention they have received?	Yes = 1; No = 0;	
	For studies where the patients would have no way of knowing which intervention they received, this should be	Unable to determine = 0	
	answered yes.		
7.	Were the statistical tests used to assess the main outcomes appropriate?	Yes = 1; No = 0;	
	The statistical techniques used must be appropriate to the data. For example nonparametric methods should be use	ed Unable to determine = 0	
	for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias,		
	the question should be answered yes. If the distribution of the data (normal or not) is not described, it must be		
	assumed that the estimates used were appropriate and the question should be answered yes.		
8.	Were the main outcome measures used accurate (valid and reliable)?	Yes = 1; No = 0;	
	For studies where the outcome measures are clearly described, the question should be answered yes. For studies	Unable to determine = 0	
	that refer to other work or demonstrates the outcome measures are accurate, the question should be answered yes		
Internal validity - confounding (selection bias)			
9.	Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls	Yes = 1; No = 0;	
	(case-control studies) recruited from the same population?	Unable to determine = 0	
	For example, patients for all comparison groups should be selected from the same hospital. The question should be		
	answered unable to determine for cohort and case control studies where there is no information concerning the		
	source of patients included in the study.		
10	. Were study subjects in different intervention groups (trials and cohort studies) or were the cases and	Yes = 1; No = 0;	
	controls (case-control studies) recruited over the same period of time?	Unable to determine = 0	
	For a study which does not specify the time period over which patients were recruited, the question should be		

encurerad on "unable to determine"

answered as "unable to determine."

11. Were study subjects randomized to intervention groups?

Studies which state that subjects were randomized should be answered yes, except where method of randomization **U** would not ensure random allocation. For example, alternate allocation would score 0 because it is predictable.

12. Were losses of patients to follow-up taken into account?

If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine.

If the proportion lost to follow-up was too small to affect the main findings, the question should be answered yes.

1. Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. J Epidemiol Community Health. 1998;52(6):377-84.

Yes = 1; No = 0;

Unable to determine = 0

Yes = 1; No = 0;

Unable to determine = 0