|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Appendix 1- A general framework for the evaluation of clinical trial quality** | | | | | | | | | | |
| **Study**  **Item** | Mirmiran et al. 2012 | Mirmiran et al. 2014 | Christiansen et al. 2010 | Lopez-Chillon et al. 2018 | Axelsson et al. 2017 | Murashima et al. 2004 | Kikuchi et al. 2015 | Bahadoran et al. 2012 | Bahadoran et al. 2012 | Bahadoran et al. 2010 |
| Was the study described as randomized (this includes words such as randomly, random, and randomization)? | 1 | 1 | 1 | 0 | 1 | 0 | 1 | 1 | 1 | 1 |
| Was the method used to generate the sequence of randomization described and appropriate  (Table of random numbers, computer-generated, etc)? | 1 | 1 | 1 | 0 | 1 | 0 | 1 | 1 | 1 | 1 |
| Was the study described as double blind? | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 1 | 1 |
| Was the method of double blinding described and appropriate (identical placebo, active placebo, dummy, etc)? | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 1 | 1 |
| Was there a description of withdrawals and dropouts? | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 1 |
| Deduct one point if the method used to generate the sequence of randomization was described and it was inappropriate (patients were allocated alternately, or according to date of birth, hospital number, etc). | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Deduct one point if the study was described as double blind but the method of blinding was inappropriate (e.g., comparison of tablet vs. injection with no double dummy). | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total score | 5 | 3 | 3 | 1 | 5 | 0 | 5 | 5 | 5 | 5 |