**Supplementary Table 1: Risk of bias in individual studies**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Sequence generation** | **Allocation concealment** | **Blinding of participants and personnel** | **Blinding of outcome assessors** | **Incomplete outcome data** | **Selective outcome data** | **Other sources of bias / Comments** |
| Al-Hosni 2012 | unclear | unclear | low | low | low | low | randomisation process not defined, hence unclear |
| Bin-Nun 2005 | unclear | unclear | low | low | low | low | randomisation process not defined, hence unclear |
| Costeloe 2015 | low | low | low | low | low | low |  |
| Dani 2002 | unclear | low | low | unclear | low | low | used envelopes but not reported how sequence was generated, says double blind but blinding procedures not described, likely most relevant for outcome assessment |
| Demirel 2013 | low | low | low | low | low | low |  |
| Fernandez-Carrocera 2013 | low | unclear | low | low | low | low |  |
| Jacobs 2013 | low | low | low | low | low | low |  |
| Lin 2008 | low | unclear | low | unclear | low | low | assignment sent to principal investigator when eligible patient so 'unclear'; NEC as an outcome defined blind but not stated for other outcomes and local PI knew assignment |
| Lin 2005 | unclear | low | low | unclear | low | low | NEC as an outcome was defined blind but not stated for other outcomes and local PI  |
| Manzoni 2006 | low | unclear | high | high | low | low | clinical staff do not appear to have been blinded |
| Oncel 2014 | low | low | unclear | unclear | low | low |  |
| Rouge 2009 | low | low | unclear | unclear | low | low |  |
| Saengtawesin 2014 | low | unclear | unclear | unclear | low | low |  |
| Sari 2011 | low | low | low | low | low | low | low for NEC, unclear for other outcomes |
| Serce 2013 | low | low | low | unclear | low | low |  |
| Tewari 2015 | low | low | low | low | low | low |  |
| Totsu 2014 | low | unclear | unclear | unclear | low | low | Cluster randomized, stated double-blind but hospital allocation concealment not clear |
| Van Niekerk 2015 | low | unclear | low | low | low | low |  |
| Xu 2016 | unclear | unclear | medium | medium | low | low | Staff administering product not involved in care but not clear who assessed outcomes |