**Supplementary File 5 – Risk of Bias Assessments**

**Risk of Bias in Case Series**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Design | Cases | Intervention | Outcome | Follow-up | Well described results |  |
| Study | Clear objective | Specified inclusion criteria | Representative | Consecutive | Adequate number | Consistent | Treatment ascertainment1 | Robust measures | Blinded assessment | Duration | Completeness | Quality of Evidence |
| Dalton (1993) (12) | - | + | + | ? | + | - | + | ? | - | + | + | + | Very Low |
| Berns and Zietlow (1998) (59) | + | + | ? | + | - | - | + | - | - | + | + | - | Very Low |
| Barkana *et al* (1999) (14) | - | + | + | + | + | - | + | + | - | + | + | + | Very Low |
| Prause *et al* (1999) (52) | - | - | + | ? | - | + | + | ? | - | - | + | - | Very Low |
| Badjie *et al* (2012) (38) | - | + | - | + | - | - | + | - | - | - |  | - | Very Low |
| Higgins *et al* (2012) (55) | - | - | ? | + | - | + | + | + | - | + | + | + | Very Low |
| Chew *et al* (2013) (51) | + | - | + | + | + | - | + | + | - | - | + | - | Very Low |
| Mena-Mundoz (2013) (74) | - | - | - | + | + | + | + | - | - | - | + | - | Very Low |
| Sherren & Burns (2013) (25) | - | - | + | + | + | + | + | - | - | - | + | - | Very Low |
| Malsby *et al* (2013) (15) | - | + | + | ? | - | - | + | - | - | - | - | + | Very Low |
| Glassberg *et al* (2013) (67) | + | + | + | + | - | + | + | + | - | + | + | + | Very Low |
| Weaver *et al* (2013) (23) | - | + | + | + | + | + | + | + | - | + | + | + | Very Low |
| Bodnar *et al* (2014) (50) | + | + | + | + | + | + | + | + | - | + | + | + | Very Low |
| O’Reilly *et al* (2014) (41) | + | + | + | + | + | + | + | + | - | + | + | + | Very Low |
| Chen (2014) (74) | + | + | ? | + | + | + | + | ? | - | - | ? | + | Very Low |
| Powell-Dunford (2014) (54) | - | + | + | ? | + | - | + | - | - | - | - | - | Very Low |
| Sunde *et al* (2015) (53) | + | + | + | + | - | + | + | + | - | + | + | + | Very Low |
| 1Treatment ascertainment assumed to be satisfactory due to haemovigilance requirements |

Risk of Bias in Comparative Studies (Newcastle-Ottawa Scale)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Cohorts |  | Controls for |  | Follow-up |  |
| Study | PHBP-recipients representative | Non-recipients from same population | Treatment ascertainment1 | Outcome absent before treatment | Injury Severity2 | ≥1 other factor | Outcome by record linkage | Duration | Completeness | Quality of Evidence |
| Price *et al* (1999) (49) | + | - | + | + | + | + | + | - | + | Very Low |
| Sumida *et al* (2000) (48) | + | + | + | - | - |  | + | - | + | Very Low |
| Kim *et al* (2012) (37) | - | - | + | + | - | - | + | + | + | Very Low |
| Badjie *et al* (2013) (39) | - | - | + | + | - | - | + | + | + | Very Low |
| Wheeler *et al* (2013) (57) | + | + | + | - | - | - | + | + | + | Very Low |
| Gross *et al* (2014) (56) | + | + | + | - | - | - | + | + | + | Very Low |
| O’Reilly *et al* (2014) (40) | - | - | + | + | + | - | + | + | + | Very Low |
| Smith *et al* (2014) (46) | + | - | + | + | + | + | + | + | + | Very Low |
| Brown *et al* (2015) (35) | + | + | + | + | + | + | + | + | + | Low |
| Brown *et al* (2015) (36) | + | + | + | + | + | + | + | + | + | Low |
| 1Treatment ascertainment assumed to be satisfactory due to haemovigilance requirements2Statistical correction or case matching |