**Figure RoB 2 Excel Marco Form Manual (Beta Version 7)**



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| **Unique ID** | 3LB\_vs\_CAorP | **Study ID** | 58 | **Assessor** | LF |
| **Ref or Label** | Gorfine 2011 | **Aim** | assignment to intervention (the 'intention-to-treat' effect) |  |  |
| **Experimental** | Liposomal Bupivacaine | **Comparator** | Placebo | **Source** | Journal article(s) |
| **Outcome** | Adverse effect | **Results** |  | **Weight** | 1 |
| **Domain** | **Signalling question** | | | **Response** | **Comments** |
| **Bias arising from the randomization process** | 1.1 Was the allocation sequence random? | | | Y |  |
| 1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions? | | | PY |
| 1.3 Did baseline differences between intervention groups suggest a problem with the randomization process? | | | PN |  |
| **Risk of bias judgement** | | | **Low** |  |
| **Bias due to deviations from intended interventions** | 2.1.Were participants aware of their assigned intervention during the trial? | | | PN |  |
| 2.2.Were carers and people delivering the interventions aware of participants' assigned intervention during the trial? | | | N |
| 2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context? | | | NA |  |
| 2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome? | | | NA |  |
| 2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups? | | | NA |  |
| 2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention? | | | Y |  |
| 2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized? | | | NA |  |
| **Risk of bias judgement** | | | **Low** |  |
| **Bias due to missing outcome data** | 3.1 Were data for this outcome available for all, or nearly all, participants randomized? | | | Y |  |
| 3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data? | | | NA |  |
| 3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value? | | | NA |  |
| 3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value? | | | NA |
| **Risk of bias judgement** | | | **Low** |  |
| **Bias in measurement of the outcome** | 4.1 Was the method of measuring the outcome inappropriate? | | | N |  |
| 4.2 Could measurement or ascertainment of the outcome have differed between intervention groups? | | | PN |  |
| 4.3 Were outcome assessors aware of the intervention received by study participants? | | | N |  |
| 4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received? | | | NA |  |
| 4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received? | | | NA |
| **Risk of bias judgement** | | | **Low** |  |
| **Bias in selection of the reported result** | 5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis? | | | Y |  |
| 5.2 ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain? | | | PN |  |
| 5.3 ... multiple eligible analyses of the data? | | | PN |  |
| **Risk of bias judgement** | | | **Low** |  |
| **Overall bias** | **Risk of bias judgement** | | | **Low** |  |
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| **Unique ID** | 2LB\_vs\_CAorP | **Study ID** | 60 | **Assessor** | LF |
| **Ref or Label** | Haas 2012 | **Aim** | assignment to intervention (the 'intention-to-treat' effect) |  |  |
| **Experimental** | Liposomal Bupivacaine | **Comparator** | Placebo | **Source** |  |
| **Outcome** | Adverse effect | **Results** |  | **Weight** | 1 |
| **Domain** | **Signalling question** | | | **Response** | **Comments** |
| **Bias arising from the randomization process** | 1.1 Was the allocation sequence random? | | | Y |  |
| 1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions? | | | PY |
| 1.3 Did baseline differences between intervention groups suggest a problem with the randomization process? | | | PY |  |
| **Risk of bias judgement** | | | **Some concerns** |  |
| **Bias due to deviations from intended interventions** | 2.1.Were participants aware of their assigned intervention during the trial? | | | PN |  |
| 2.2.Were carers and people delivering the interventions aware of participants' assigned intervention during the trial? | | | N |
| 2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context? | | | NA |  |
| 2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome? | | | NA |  |
| 2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups? | | | NA |  |
| 2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention? | | | PY |  |
| 2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized? | | | NA |  |
| **Risk of bias judgement** | | | **Low** |  |
| **Bias due to missing outcome data** | 3.1 Were data for this outcome available for all, or nearly all, participants randomized? | | | Y |  |
| 3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data? | | | NA |  |
| 3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value? | | | NA |  |
| 3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value? | | | NA |
| **Risk of bias judgement** | | | **Low** |  |
| **Bias in measurement of the outcome** | 4.1 Was the method of measuring the outcome inappropriate? | | | N |  |
| 4.2 Could measurement or ascertainment of the outcome have differed between intervention groups? | | | PN |  |
| 4.3 Were outcome assessors aware of the intervention received by study participants? | | | PN |  |
| 4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received? | | | NA |  |
| 4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received? | | | NA |
| **Risk of bias judgement** | | | **Low** |  |
| **Bias in selection of the reported result** | 5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis? | | | PN |  |
| 5.2 ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain? | | | PN |  |
| 5.3 ... multiple eligible analyses of the data? | | | PN |  |
| **Risk of bias judgement** | | | **Some concerns** |  |
| **Overall bias** | **Risk of bias judgement** | | | **Some concerns** |  |
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| **Unique ID** | 1LB\_vs\_CAorP | **Study ID** | 92 | **Assessor** | LF |
| **Ref or Label** | Miller 2009 | **Aim** | assignment to intervention (the 'intention-to-treat' effect) |  |  |
| **Experimental** | Liposomal Bupivacaine | **Comparator** | Bupivacaine HCL with epinephrine | **Source** |  |
| **Outcome** | Adverse effect | **Results** |  | **Weight** | 1 |
| **Domain** | **Signalling question** | | | **Response** | **Comments** |
| **Bias arising from the randomization process** | 1.1 Was the allocation sequence random? | | | Y |  |
| 1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions? | | | PY |
| 1.3 Did baseline differences between intervention groups suggest a problem with the randomization process? | | | PN |  |
| **Risk of bias judgement** | | | **Low** |  |
| **Bias due to deviations from intended interventions** | 2.1.Were participants aware of their assigned intervention during the trial? | | | PN |  |
| 2.2.Were carers and people delivering the interventions aware of participants' assigned intervention during the trial? | | | PN |
| 2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the experimental context? | | | NA |  |
| 2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome? | | | NA |  |
| 2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups? | | | NA |  |
| 2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention? | | | PY |  |
| 2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized? | | | NA |  |
| **Risk of bias judgement** | | | **Low** |  |
| **Bias due to missing outcome data** | 3.1 Were data for this outcome available for all, or nearly all, participants randomized? | | | NI |  |
| 3.2 If N/PN/NI to 3.1: Is there evidence that result was not biased by missing outcome data? | | | N |  |
| 3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value? | | | PN |  |
| 3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value? | | | NA |
| **Risk of bias judgement** | | | **Low** |  |
| **Bias in measurement of the outcome** | 4.1 Was the method of measuring the outcome inappropriate? | | | PN |  |
| 4.2 Could measurement or ascertainment of the outcome have differed between intervention groups? | | | PN |  |
| 4.3 Were outcome assessors aware of the intervention received by study participants? | | | PN |  |
| 4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received? | | | NA |  |
| 4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received? | | | NA |
| **Risk of bias judgement** | | | **Low** |  |
| **Bias in selection of the reported result** | 5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis? | | | PY |  |
| 5.2 ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain? | | | NI |  |
| 5.3 ... multiple eligible analyses of the data? | | | PN |  |
| **Risk of bias judgement** | | | **Some concerns** |  |
| **Overall bias** | **Risk of bias judgement** | | | **Some concerns** |  |