## 1 Intravenous midazolam compared to intravenous placebo for sedation before procedures

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Intravenous midazolam compared to placebo for sedation before procedures** | | | | | | |
| **Patient or population:** Adults requiring sedation before gastrointestinal endoscopy and bronchoscopy, adults requiring nasogastric tube insertion in an emergency department and children  **Settings:** Hospitals in India, Iran, UK, Portugal, United States and Japan **Intervention:** Intravenous midazolam **Comparison:** Placebo | | | | | | |
| **Outcomes** | **Illustrative comparative risks\* (95% CI)** | | **Relative effect (95% CI)** | **No of Participants (studies)** | **Quality of the evidence (GRADE)** | **Comments** |
| **Assumed risk** | **Corresponding risk** |
| **Placebo** | **Intravenous midazolam** |
| **Level of sedation on a sedation assessment scale**  The Ramsay scale was used (numerical scale that ranged from 1 to 6 with higher scores indicating the participant was more sedated) | 1.19 | 1 higher  (from 0.6 higher to 1.4 higher |  | 100  (1 study) | **low**1  ⊕⊕⊝⊝ |  |
| **Numeric rating of anxiety or number of participants rated as anxious**  Number of participants rated as anxious. | **333 per 1000** | **143 per 1000**  (30 to 663) | **RR 0.43**  (0.09 to 1.99) | 123  (2 studies) | **low2**  ⊕⊕⊝⊝ |  |
| **Proportion of incomplete procedures or where there was difficulty performing the procedures** | **216 per 1000** | **108 per 1,000**  (63 to 186) | **RR 0.50**  (0.29 to 0.86) | 223  (3 studies) | **low3**  ⊕⊕⊝⊝ |  |
| **Discomfort/pain** | **168 per 1000** | **86 per 1000**  (42 to 175) | **RR 0.51**  (0.25 to 1.04) | 190  (2 studies) | **low4**  ⊕⊕⊝⊝ |  |
| \*The basis for the **assumed risk** is the control group risk across studies or the average risk for pooled data and the control group risk for single studies. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI). **CI:** Confidence interval; **RR:** Risk ratio. | | | | | | |
| GRADE Working Group grades of evidence **High quality:** Further research is very unlikely to change our confidence in the estimate of effect. **Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. **Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. **Very low quality:** We are very uncertain about the estimate. | | | | | | |

###### Footnotes

1Downgraded two levels due to concerns about the risk of bias (it was unclear how the allocation sequence was generated and concealed and how participants were blinded to the allocation) and imprecision (optimal information size was not met ‐ single study with a small number of participants, no confidence intervals were reported).

2Downgraded two levels due to concerns about risk of bias (it was unclear in one study how the allocation sequence was generated and concealed and how participants were blinded to the allocation) and imprecision (optimal information size was not met ‐ single study with a small number of participants, wide confidence intervals crossing the line of no effect, and including the potential for both benefit and harm)

3Downgraded two levels due to concerns about the risk of bias (it was unclear in one study how the allocation sequence was concealed) and imprecision (optimal information size was not met ‐ wide confidence intervals including the potential for a very large benefit or very small degree of harm)

4Downgraded two levels due to concerns about the risk of bias (it was unclear in one study how the allocation sequence was concealed) and imprecision (optimal information size was not met ‐ wide confidence intervals including the potential for a very large benefit or very small degree of harm)