## Table 4 Oral midazolam compared to oral placebo for sedation before procedures

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Oral midazolam compared to oral placebo for sedation before procedures** | | | | | | |
| **Patient or population:** Children requiring sedation before micturating cystourethrograms, and Kirschner wire removal, and adults undergoing endoscopy **Settings:** X-ray department in Turkey, orthopaedic outpatient department in UK, and endoscopy suites in USA and Thailand **Intervention:** oral 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** | **Midazolam** |
| **Level of sedation on a sedation assessment scale** (as defined/measured by the authors of the trial) |  |  |  |  |  | No studies reported on this outcome. |
| **Numeric rating of anxiety or number of participants** **rated as anxious** (as defined/measured by the authors of the trial) | 4.62  (measured on a scale that ranged from  0 to 10 with higher scores representing worse anxiety) | MD was **1.9 lower** (3.5 lower to 0.3 lower) |  | 436 (4) | **low**1  ⊕⊕⊝⊝ | The assumed and corresponding risks were estimated from the SMD, which was -1 (95% CI -1.86 to -0.16). |
| **Proportion of incomplete procedures or where there was difficulty performing the procedures** (as defined/measured by the authors of the trial) |  |  |  | 439  (4 studies) | **low**1  ⊕⊕⊝⊝ | Relative effect was not able to be conducted because there was only one incomplete procedure in the midazolam group in one of the four trials that reported on this outcome. |
| **Discomfort/Pain**  (**as defined/measured by the authors of the trial)**  Scores ranged from 0 to 10 with higher score indicating more pain | 4.62 | MD was **2 lower** (2.5 lower to 1.6 lower) |  | 99  (1 study) | **moderate**1  ⊕⊕⊕⊝ |  |
| \*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 and imprecision.

2Studies in this comparison used different instruments to measure anxiety. We used the SMD for meta-analysis. We selected the [Puttapitakpong 2015](#STD-Puttapitakpong-2015) trial as our representative study in order to calculate the assumed risk and corresponding risk for the summary of findings table. The standard deviation for the placebo group in this study was 1.9, measured on a scale ranging from 0 to 10.

2Downgraded one level due to concerns about the risk of bias.