Table 66: Heisler 2013[203]

Study	Heisler 2013[203]
Study type	RCT (Patient randomised; Parallel).
Number of studies (number of participants)	Single centre (n=137)
Countries and setting	Conducted in USA.
Line of therapy	Not applicable.
Duration of study	Intervention + follow up: 4 hours.
Method of assessment of guideline condition	Unclear method of assessment/diagnosis.
Stratum	Overall.
Subgroup analysis within study	Not applicable.

Inclusion criteria	Terminally ill people who developed audible respiratory tract secretions with a noise intensity score of at least 1 (audible only very close to the patient). They were required to be capable of or have an acceptable surrogate capable of providing informed consent.
Exclusion criteria	People were excluded if they had been treated with other antimuscarinic medications within the current inpatient admission.
Age, gender and ethnicity	Age - Mean (SD): 77.2 (11.5). Gender (M:F): 51/86. Ethnicity:
Extra comments	Diagnosis - cancer (43.1%); Baseline noise score (ranging from 0 - inaudible to 3 - clearly audible at about 20 feet): 1 (19%); 2 (58%); 3 (23%)
Indirectness of population	No indirectness
Interventions	(n=74) Intervention 1: Muscarinic acetylcholine receptor antagonist - Atropine. One-time dose sublingually. Two drops of atropine (1 mg). Duration One-time dose. Concurrent medication/care: Not explicitly specified. (n=63) Intervention 2: Placebo. Saline. Duration One-time. Concurrent medication/care: Not explicitly stated.
Funding	No funding (The authors declared no conflicts of interest).

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: ATROPINE versus PLACEBO

Protocol outcome 1: Subjective or objective improvement in respiratory secretions at hours/days
- Actual outcome: Reduction (1 point or more) on a 4 point scale at 4 hours; Group 1: 27/68, Group 2: 31/60; Risk of bias: Low; Indirectness of outcome: No indirectness.
- Actual outcome: Reduction (1 point or more) on a 4 point scale at 2 hours; Group 1: 28/74, Group 2: 26/63; Risk of bias: Low; Indirectness of outcome: No indirectness.

Protocol outcomes not reported by the study	Quality of life at hours/days; Hospitalisation at hours/days; Subjective ratings from people on distress related to noisy breathing /respiratory secretions at hours/days; Sedation (patient-rated, clinician-rated, carer-rated) at hours/days; Adverse events (particularly paradoxical agitation, failure to expectorate, dry mouth at hours/days; Subjective ratings from informal carers' on distress relating to noisy breathing/respiratory secretions at hours/days; Hydration status at hours/days; Length of survival at hours/days; Length of stay at hours/days.