Table 54: Bruera et al 2005. trial: Bruera 2005[73]

Study	Bruera et al 2005. trial: Bruera 2005[73]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=51)
Countries and setting	Conducted in USA; Setting: Multicentre trial based in hospitals.
Duration of study	Intervention + follow up: 2 days
Method of assessment of guideline condition	Adequate method of assessment/diagnosis.
Stratum	Cancer.
Subgroup analysis within study	Not applicable: Not done.
Inclusion criteria	A diagnosis of advanced cancer with no further treatment planned; an oral intake of less the 1000 ml/day; evidence of mild to moderate dehydration (decreased skin turgor in subclavicular region more than 2 seconds, plus at least 1 of the following findings: dry mouth, thirst, decreased volume of urine, in the absence of reasons for jaundice or haematuria, and biochemical values consistent with dehydration).
Exclusion criteria	Refusal to participate. The presence of severe dehydration, defined as a decreased systolic resting BP 30 mmHg or lower from baseline value, low perfusion of limbs and no UO for 12 hours or longer, a decreased level of consciousness or evidence of severe renal failure or bilateral hydronephrosis.
Recruitment/selection of patients	Not mentioned.
Age, gender and ethnicity	Age - Mean (range): 63 years (28-90 years). Gender (M:F): 24:27.
Indirectness of population	No indirectness: Compares intervention with control on symptom control using appropriate scales.
Interventions	(n=28) Intervention 1: Clinically assisted hydration - Parenteral hydration. 1000 ml of normal saline given over 4 hours, once daily. Duration 2 days. Concurrent medication/care: Given IV if IV access available, subcutaneous if no IV access

	available. (n=23) Intervention 2: Placebo - Clinically insignificant amounts. 100 ml of normal saline. Duration 2 days. Concurrent medication/care: IV if IV access available, subcutaneous if no IV access

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PARENTERAL HYDRATION VERSUS CLINICALLY INSIGNIFICANT AMOUNTS

Protocol outcome 1: Quality of life
- Actual outcome for cancer: Global patient perception of benefit at 2 days; Group 1: mean 3.8 1-7 scale rating (SD 2.2); n=27, Group 2: mean 3.6 1-7 scale rating (SD 2.4); n=22; Overall wellbeing 1-7 Top=High is good outcome; Risk of bias: High; Indirectness of outcome: No indirectness
- Actual outcome for cancer: Global investigators perception of benefit at 2 days; Group 1: mean 4.5 1-7 (SD 2.3); n=27, Risk of bias: High; Indirectness of outcome: No indirectness
- Actual outcome for cancer: Patients perception of wellbeing at 2 days; Group 1: mean 1.4 (SD 4.1); n=27, Group 2: mean 0.8 (SD 3.1); n=22; Perception of wellbeing 1-10 Top=High is good outcome; Risk of bias: High; Indirectness of outcome: No indirectness
- Actual outcome for cancer: Investigators perception of wellbeing at 2 days; Group 1: mean 1.2 (SD 3.9); n=27, Group 2: mean 0.9 (SD 2.7); n=22; Quality of life 1 (worst possible) -10 (best possible) Top=High is good outcome; Risk of bias: High; Indirectness of outcome: No indirectness

Protocol outcome 2: Symptom improvement
- Actual outcome for cancer: hallucinations at 2 days; Group 1: 9/11, Group 2: 7/14; Risk of bias: High; Indirectness of outcome: No indirectness
- Actual outcome for cancer: sedation at 2 days; Group 1: 15/18, Group 2: 5/15; Risk of bias: High; Indirectness of outcome: No indirectness
- Actual outcome for cancer: myoclonus at 2 days; Group 1: 15/18, Group 2: 8/17; Risk of bias: High; Indirectness of outcome: No indirectness
- Actual outcome for cancer: symptoms totalled together at 2 days; Risk of bias: High; Indirectness of outcome: No indirectness

Protocol outcome 3: Adverse events procedural at end of study
- Actual outcome for cancer: Pain at injection site at 2 days; Group 1: mean 1.41 (SD 2.9); n=27, Group 2: mean 1.75 (SD 2.55); n=22; Risk of bias: High; Indirectness of outcome: No indirectness
- Actual outcome for cancer: swelling at injection site at 2 days; Group 1: mean 0.82 (SD 1.13); n=27, Group 2: mean 1.41 (SD 1.66); n=22; NRS 0-10 Top=--; Risk of bias: High; Indirectness of outcome: No indirectness