Table 55: Bruera et al 2013 trial: Bruera 2013[68]

Study	Bruera et al 2013 trial: Bruera 2013[68]

Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	(n=129)
Countries and setting	Conducted in USA, Setting: Home
Duration of study	Intervention time: 7 days
Stratum	Cancer
Subgroup analysis within study	Not applicable
Inclusion criteria	Aged>18. Admitted to hospice. Reduced oral intact of fluids with evidence of mild or moderate dehydration as defined by a) decreased skin turgor in subclavicular region (2 seconds) and a score of >2 of 5 in the clinical dehydration assessment. Intensity of >1 on a 0 to 10 scale for fatigue and 2 of the 3 other target symptoms (hallucinations, sedation and myoclonus). Life expectancy 1 week. Availability of a primary carer. MDAS score <13. Ability to give written informed consent. Geographic accessibility (within 60 miles of the University of Texas MD Anderson Cancer Centre.
Exclusion criteria	Severe dehydration defined as decreased blood pressure or low perfusions of limbs, decreased level of consciousness or no urine output for 12 hour, history or clinical evidence of renal failure with creatinine more than 1.5 x upper normal limit, history or clinical evidence of congestive heart failure, or history of bleeding disorders demonstrated by clinical evidence of active bleeding, haematuria, hematoma, ecchymoses, and petechiae.
Recruitment/selection of patients	Recruited from inpatients at hospice within the geographical area of MD Anderson Cancer Centre.
Age, gender and ethnicity	Age - Mean (range): 67 (41-92). Gender (M:F): 68:61
Indirectness of population	No indirectness.
Interventions	(n=63) Intervention 1: Clinically assisted hydration - Parenteral hydration. 1000 ml normal saline administered subcutaneously over 4 hours daily. Duration 7 days. Concurrent medication/care: usual palliative care, visited daily by research nurse to start fluids. (n=66) Intervention 2: Placebo - Clinically insignificant amounts. 100 ml of normal saline administered subcutaneously over 4 hours, daily. Duration 7 days. Concurrent medication/care: Usual palliative care received, and daily visits from the research nurse to start the infusion.
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: Quality of life using FACT G scale. Measured difference at baseline and 7 days; Group 1: mean 6.7 (SD 11.2); n=44, Risk of bias: Low; Indirectness of outcome: Serious indirectness

Protocol outcome 2: Symptom improvement
- Actual outcome for cancer: Global symptom evaluation. Measured difference at baseline and 7 days; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome for cancer: Change in the sum of 4 dehydration symptoms at difference at baseline and 7 days; Group 1: mean -4.9 (SD 9.2); n=44, Group 2: mean -3.8 (SD 9.05); n=49; ESAS composite for fatigue, drowsiness, hallucinations and myoclonus 1-10 for each outcome, 4-40 Top=High is poor outcome; Risk of bias: Low; Indirectness of outcome: No indirectness
outcome; Risk of bias: low; Indirectness of outcome: No indirectness

Protocol outcome 3: Adverse symptoms related to dehydration at end of study
- Actual outcome for cancer: Delirium using MDAS score at difference at baseline and 7 days; Risk of bias; Indirectness of outcome: No indirectness
- Actual outcome for cancer: Delirium using NuDESC score at difference at baseline and 7 days; Risk of bias: Low; Indirectness of outcome: No indirectness

Protocol outcome 4: Hydration assessment
- Actual outcome for cancer: change in dehydration assessment score difference at baseline and 7 days.; Group 1 mean -1 (SD 1.7) n=44; Group 2 -0.5 (SD 1.4) n=49 Risk of bias: high; Indirectness of outcome: No indirectness

Protocol outcome 5: Biochemistry at end of study
- Actual outcome for cancer: change in urea difference at baseline and 7 days.; Group 1 median -2 (range -7 to 3) n=44; Group 2, median 2 (range -1 to 8) n=49 Risk of bias: very high; Indirectness of outcome: No indirectness
- Actual outcome for cancer: change in sodium difference at baseline and 7 days.; Group 1 mean 1.9 (SD 5.0) n=44; Group 2 0.7 (SD 5.0) n=49 Risk of bias: very high; Indirectness of outcome: No indirectness
- Actual outcome for cancer: change in creatinine difference at baseline and 7 days.; Group 1 median -0.1 (range -0.2 to 0) n=44; Group 2 –0.1 (range -0.1 to 0.1) n=49 Risk of bias: very high; Indirectness of outcome: No indirectness

Protocol outcome 6: Survival at end of study
Actual outcome for cancer, survival; Group 1 median 21 (range 13 to 29) n=44; Group 2, median 15 (range 12 to 18) n=49 Risk of bias: very high; Indirectness of outcome: No indirectness