Table 57: Morita et al 2005 trial: Morita 2005[327]

Study	Morita et al 2005 trial: Morita 2005[327]
Study type	Prospective cohort study
Number of studies (number of participants)	(n=226)
Countries and setting	Conducted in Japan; Setting: oncology units, palliative/home care settings.
Duration of study	21 days
Stratum	Cancer
Inclusion criteria	Age >20 years; life expectancy estimated by a physician to be <3 months; and incurable malignancy of abdominal origin
Exclusion criteria	Liver cirrhosis of any aetiology, renal failure, nephrotic syndrome, protein losing enteropathy, intra-abdominal shunt for ascites, hypercalcaemia, adrenalopathy, thyroid diseases, and other complications of the circulatory, respiratory, hepatic, or renal system unrelated to underlying malignancies. Surgical, radiological or oncological treatments with the primary intent of tumour reduction in the 3 weeks prior to study inclusion; existing communication difficulty such as aphasia or aphonia; and the use of assisted enteral nutrition.
Recruitment/selection of patients	From patients already being treated at the institutions.
Age, gender and ethnicity	Age - Mean (SD): 68. Gender (M:F): 101:109.
Indirectness of population	No indirectness.
Interventions	(n=59) Intervention 1: Clinically assisted hydration - Parenteral hydration. More than 1 litre/ day of clinically assisted hydration or more at both 1 week and 3 weeks before death. Duration 3 weeks. Concurrent medication/care: Usual Care

	Further details: 1. Route of administration: 2. Volume of fluid administered: (n=167) Intervention 2: Placebo - Clinically insignificant amounts. People who received less the 1/day of clinically assisted hydration at both 1 week and 3 weeks before death. Duration 3 weeks. Concurrent medication/care: Usual treatment Further details: 1. Route of administration: 2. Volume of fluid administered:
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PARENTERAL HYDRATION VERSUS CLINICALLY INSIGNIFICANT AMOUNTS Protocol outcome 1: Adverse symptoms related to dehydration at end of study - Actual outcome for cancer: Hyperactive delirium at 3 weeks; Group 1: 7/59, Group 2: 22/167; Risk of bias: Very high; Indirectness of outcome: serious Protocol outcome 2: Adverse events, over hydration at end of study - Actual outcome for cancer: Pleural effusion at 3 weeks; Group 1: mean 0.36 (SD 0.61); n=59, Group 2: mean 0.31 (SD 0.63); n=167; Pleural effusion score 0-2 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: serious - Actual outcome for cancer: Oedema at 3 weeks; Group 1: mean 6.1 (SD 6.4); n=59, Group 2: mean 5.2 (SD 5.2); n=167; Peripheral oedema score 0-21 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: serious Protocol outcome 3: Hydration status at end of study Actual outcome for cancer: Dehydration assessment Group 1: mean 2.7 (SD 1.6); n=59, Group 2: mean 3.2 (SD 1.5); n=167; Ad hoc dehydration score 0-5 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: serious Protocol outcome 4: Biochemistry at end of study Actual outcome for cancer: Urea/creatinine, Group 1: mean 44 (SD 18); n=37, Group 2: mean 39 (SD 20); n=56; urea/creatinine mg/dl, Risk of bias: Very high; Indirectness of outcome: serious	