Table 58: Viola 1997 trial: Viola 1997[450]

Study	Viola 1997 trial: Viola 1997[450]
Study type	Prospective cohort study
Number of studies (number of participants)	(n=66)
Countries and setting	Conducted in Canada; Setting: Hospices. Took place in 2 hospices, located in Edmonton, and Ottawa.

Duration of study	14 days
Stratum	Cancer
Subgroup analysis within study	Not applicable
Inclusion criteria	Advanced cancer. Inpatients of either Edmonton or Ottawa palliative care units with advanced cancer, not aphasic, MMSE >24, and subjectively competent (as judged by physicians), able to understand English if at the Edmonton site, or English or French at Ottawa site. Has a history of poor oral fluid intact, or excess fluid loss or both, plus a history of decreased urine output, dry mouth sensation, thirst sensation postural dizziness, or combination, or resting heart rate >100 BPM, dry mucous membranes, enophthalmos, or combination.
Exclusion criteria	Receiving enteral tube feedings, acute renal failure, pulmonary oedema, or bleeding disorders, aphasic, MMSE <24. Immediate discharge planned.
Recruitment/selection of patients	People were recruited from existing inpatients at 2 hospice sites.
Age, gender and ethnicity	Age - Mean (SD): 63.5. Gender (M:F): 29:35. Ethnicity: NA
Further population details	1. Setting: Hospice
Extra comments	Most participants were excluded because of cognitive defects. 2 from incomplete data, and 1 from a bleeding disorder
Interventions	(n=33) Intervention 1: Clinically assisted hydration - Parenteral hydration. Subcutaneous fluids titrated to participant needs. Either 0.9% NaCl, or 0.3% NaCl with 3.3% dextrose. Hyaluronidase 750 units added to each 1 litre of fluid solution. The median volume was approximately 1000 ml/day. Duration-Until death/no longer having a fluid deficit or discharge from palliative care unit. Concurrent medication/care: usual care. Further details: 1. Route of administration: Subcutaneous 2. Volume of fluid administered: 1 litre a day or more (n=33) Intervention 2: Placebo - No intervention. No administered fluids. Duration Until death/no longer having a fluid deficit or discharge from palliative care unit. Concurrent medication/care: Usual Care. Further details: 1. Route of administration: Not applicable / Not stated / Unclear. 2. Volume of fluid administered: Not applicable / Not stated / Unclear
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: PARENTERAL HYDRATION VERSUS NO INTERVENTION Protocol outcome 1: Symptom improvement - Actual outcome for cancer: Wellbeing during the afternoon at Day 14; Group 1: mean 52.5 (SD 26.4); n=17, Group 2: mean 80 (SD 21.4); n=6; Risk of bias: Very high; Indirectness of outcome: No indirectness	

- Actual outcome for cancer: Nausea during afternoon. at Day 14; Group 1: mean 23.8 (SD 30.5); n=20, Group 2: mean 21.3 (SD 40.2); n=8; VAS 1-100 Top=High is poor outcome; Risk of bias: --; Indirectness of outcome: No indirectness
- Actual outcome for cancer: Thirst during the afternoon at Day 14; Group 1: mean 47.4 (SD 32.4); n=18, Group 2: mean 61.2 (SD 12.1); n=4; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome for cancer: Anxiety during the afternoon at Day 14; Group 1: mean 17 (SD 19); n=20, Group 2: mean 27.5 (SD 34.5); n=6; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome for cancer: Pain during the afternoon at Day 14; Group 1: mean 20 (SD 15.3); n=20, Group 2: mean 29.4 (SD 27.2); n=8; Risk of bias: Very high; Indirectness of outcome: No indirectness
- Actual outcome for cancer: Dyspnoea during afternoon at Day 14; Group 1: mean 20.9 (SD 24); n=20, Group 2: mean 12.9 (SD 24.8); n=7; VAS 1-100 Top=High is poor outcome; Risk of bias: Very high; Indirectness of outcome: No indirectness