

Does fluid administration in the terminally ill reduce the frequency and amount of sedation required for the management of agitation /restlessness?

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
23/01/2004	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
23/01/2004	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
16/06/2014	Signs and Symptoms	<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

RRCC850F RATHBONE

Study information

Scientific Title

Study objectives

Aims:

1. Identify the frequency of agitation/restlessness for which a treatable cause cannot be found
2. Identify whether fluid status has any association with terminal agitation and restlessness
3. Identify whether the administration of fluid affects the amounts of sedation which need to be prescribed for the management of agitation/restlessness
4. Provide evidence for current clinical decision making and direction for future studies

Hypothesis:

There is no difference in the frequency or quality of agitation/restlessness in patients with a very short life expectancy whose oral fluid intake has fallen below 1000 ml/24 hours and are administered 1 litre of normal saline subcutaneously in 24 hours and those who are not.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Symptoms and general pathology

Interventions

Patients are randomised following consent to receive their 'normal' care plus 1 litre of normal saline subcutaneously or just their normal care. Fluids will be administered subcutaneously using a cannulae sited following an individual assessment of the patient. The fluid will be administered over 12 hours at a time which the patient finds most convenient.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

A tool developed by Jones et al (1998) will be used in assessing the degree of agitation /restlessness which occurs. The data collection procedure will also include information on the degree of agitation, including any precipitating, aggravating or alleviating factors. Staff will therefore have to complete an assessment sheet which asks them to identify not only the

frequency and degree of agitation but also a checklist of causative factors to exclude if the patient does become agitated. These will include assessment of pain, full bladder, constipation, anguish and the need for opioid rotation.

In general the assessor will be the qualified nurse on duty and the assessment should be performed once during each shift, on a morning between 5 am and 7 am, 10 am and 12 midday and on an evening between 5 pm and 7 pm. The end point of the study will be the death of the patient or discharge if they wish to die at home.

Key secondary outcome(s)

Not provided at time of registration

Completion date

10/01/2002

Eligibility

Key inclusion criteria

Patients who meet the inclusion criteria will be identified during the daily team meetings held within each of the hospices. The inclusion criteria are as follows:

1. Deemed to have a short life expectancy (Bozetti 1996)
2. Aged above 18
3. Inpatient within Butterick Hospice, Teesside Hospice, Hartlepool Hospice, St Oswalds Hospice or the Newcastle Marie Curie Centre
4. Oral intake has fallen below 1000 ml/24 hour and is recognised by the team as part of their deterioration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Known to have cerebral oedema
2. Known to have congestive cardiac failure
3. Known to have a coagulation disorder
4. Known to be in renal or liver failure or are hypercalcaemic
5. Known to have a tumour which has a direct influence on fluid balance

Date of first enrolment

10/01/2000

Date of final enrolment

10/01/2002

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

23 Meath Way

Cleveland

United Kingdom

TS14 7PG

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type

Details

Date created **Date added** **Peer reviewed?** **Patient-facing?**

Participant information sheet

