ISRCTN28898435 https://doi.org/10.1186/ISRCTN28898435

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

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
16/06/2014

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/01/2000

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
23 Meath Way
Cleveland
United Kingdom
TS14 7PG

Sponsor information

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

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London

United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration