# 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	<ul><li>Prospectively registered</li></ul>
23/01/2004	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
23/01/2004	Completed	Results
Last Edited	Condition category	Individual participant data
16/06/2014	Signs and Symptoms	Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Mrs Joanne Rathbone

#### Contact details

23 Meath Way Hunters Hill Guisborough Cleveland United Kingdom TS14 7PG +44 (0)1287 295412

# 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