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Delirium Prevention Study

Submission date
29/04/2010

Recruitment status
No longer recruiting

Registration date
29/04/2010

Overall study status
Completed

Last Edited
22/11/2013

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof John Young

Contact details
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United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4951

Study information

Scientific Title
Comparative study of a standardised care system to prevent delirium

Study objectives
Delirium is a syndrome of acute, fluctuating confusion, which commonly affects older people who are unwell and is associated with poorer outcomes, but has the potential to be prevented.

The aim of the study is to investigate the effectiveness of a novel, multi-component intervention called the Delirium Prevention System of Care on delirium occurrence in older people admitted to hospital, thereby improving their clinical outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bradford REC, 18/09/2007, ref: 07/H1302/73

Study design
Non-randomised interventional and observational prevention cohort study

Primary study design
Observational

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Dementia; Disease: Dementia

Interventions
Control/before group:
Usual care

Intervention/after group:
Delirium prevention care system - education of all grades of ward staff about delirium and its prevention (education provided by delirium champions), staff modification of prevention protocols, use of multicomponent delirium prevention protocols multiple times a day by all staff, focused on modifying common risk factors for delirium.

Observation detail:
Daily assessments of all recruited participants for delirium using Confusion Assessment Method (CAM)

Study entry: registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Incident delirium (measured using Confusion Assessment Method score greater than 2 and Delirium Rating Scale [DRS-R-98] total score greater than 17) by 7 days after study ward admission

Secondary outcome measures
1. Cumulative length of delirium episodes per patient by ward discharge and 6 months after ward discharge
2. Number of delirium episodes per patient by ward discharge and 6 months after ward discharge

Overall study start date
05/10/2007

Completion date
30/01/2009

Eligibility

Key inclusion criteria
Admitted to one of study elderly care wards

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 500; UK Sample Size: 500

Key exclusion criteria
1. Consent or assent is refused
2. Not enrolled within 24 hours of ward admission
3. Patient leaves the ward prior to their first outcome assessment
4. Unable to speak English and there is no translator available
5. Unconscious or dying
6. Aged 73 - 104 years, either sex

Date of first enrolment

05/10/2007

Date of final enrolment
30/01/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Academic Unit of Elderly Care and Rehabilitation
Bradford
United Kingdom
BD9 6RJ

Sponsor information

Organisation
York Hospitals NHS Foundation Trust (UK)

Sponsor details
Learning and Research Centre
Wigginton Road
York
England
United Kingdom
YO31 8HE

Sponsor type
Hospital/treatment centre

Website
http://www.york.nhs.uk/

ROR
https://ror.org/027e4g787

Funder(s)

Funder type

Charity

Funder Name
Research into Ageing (UK) (ref: 293)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2013		Yes	No