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A randomised placebo-controlled trial of rivastigmine in delirium in older medical in-patients: a pilot study

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/10/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
14/07/2010	Signs and Symptoms	

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
3

Study information

Scientific Title

Study objectives
1. The duration of delirium in people aged 65 or over on admission to an acute medical care of the elderly ward, or with onset at any time 3 weeks after admission, will be significantly less when treated with rivastigmine up to 3 mg daily compared to placebo, whether or not supplemented by risperidone 1 mg in divided doses daily
2. The proportion of older people who develop a delirium postoperatively following an orthopaedic procedure will be significantly less when treated with rivastigmine up to 3 mg daily compared to placebo, whether or not supplemented by risperidone 1 mg in divided doses daily
3. The percentage of patients who experience adverse events or complications on rivastigmine compared to placebo will be significantly less than those receiving treatment as usual
4. The percentage of patients who relapse after three delirium-free days after an episode of delirium will be significantly higher in those previously treated as usual than those treated with rivastigmine
5. These differences will remain significant irrespective of pre-admission cognitive function

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Delirium

Interventions
Rivastigmine up to 1.5 mg twice a day or placebo.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Rivastigmine

Primary outcome measure
1. If develops delirium as found on Confusion Assessment Method
2. Length of delirium, measured in days

Secondary outcome measures
1. Length of admission
2. Change in mini-mental state examination score
3. Use of other psychotropic medication during treatment e.g. benzodiazepines

Overall study start date
01/04/2004

Completion date
01/07/2006

Eligibility

Key inclusion criteria
1. Patients over 65 years old
2. Admitted to elderly acute medical ward or orthopaedic ward
3. Patient has a delirium as measured on the Confusion Assessment Method or doesn't have a delirium and has a fractured neck of femur caused by trauma

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Patient already on cholinesterase inhibitor
2. Patient has had a previous adverse reaction to a cholinesterase inhibitor
3. If considered by medical team in charge of care to be in the terminal phase of illness
4. Acute chronic obstructive pulmonary disease (COPD) or asthma
5. Has a dysrhythmia on electrocardiogram (ECG)
6. Urea >20 or creatinine >200

Date of first enrolment
01/04/2004

Date of final enrolment
01/07/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
2nd Floor
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation
South Manchester University Hospitals NHS Trust (UK)

Sponsor details
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
England
United Kingdom
M23 9LT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Industry

Funder Name
Novartis (UK) - paid for tablets only

Funder Name
South Manchester University Hospitals NHS Trust (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2010		Yes	No