

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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

United Kingdom

England

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

Sponsor information

Organisation
South Manchester University Hospitals NHS Trust (UK)

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

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