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BRILiANT mood study

Submission date	Recruitment status	[ ] Prospectively registered
06/12/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/12/2012	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/01/2016	Mental and Behavioural Disorders	

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
13284

Study information

Scientific Title
Randomised pilot trial of Blood pressure Rapid Intensive Lowering And Normal Treatment for mood and cognition in persistent depression

Acronym
BRILiANT

Study objectives
This small, pilot study will look into whether rapid intensive lowering of blood pressure, in addition to participants regular antidepressant treatment, would help further improve their depression, and determine the feasibility of running a larger study involving more people at a later date. It will involve 66 people from the Northumberland, Tyne and Wear area aged between 50 and 80 years of age, with depression and raised blood pressure requiring further treatment. Participants will have up to eight visits at the Clinical Ageing Research Unit (CARU), Newcastle upon Tyne. All participants will continue with their usual antidepressants and be randomly allocated to receive either standard blood pressure treatment or intensive blood pressure treatment. Everyone will receive treatment for their blood pressure. Participants will complete questionnaires including a Beck Depression Inventory (BDI) every two weeks and MDRS at baseline, 6 and 12 weeks. A detailed neuropsychological battery and MRI scan will take place at baseline and the final 12 week outcome only. Participants will be treated until 12 weeks when investigators blind to their treatment allocation will assess the outcome measures. All participants will have their BP and depression managed by the study team throughout the trial to ensure fidelity to the treatment regimes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC, 28/08/2012, ref: 12/NE/0292

Study design
Randomised interventional treatment study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Dementias and Neurodegenerative Diseases and Depression

Interventions
Participants are randomised to receive either rapid or standard blood pressure lowering treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Depression score on the Montgomery-Asberg Depression Rating Scale (MDRS) measured at 12 weeks

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/02/2012

Completion date
29/08/2014

Eligibility

Key inclusion criteria
We will identify older adults (aged 50-80) with a history of Major Depressive Disorder (MDD) with persistent depressive symptoms who also have inadequately treated hypertension. Subjects will have a history of MDD with Hamilton depression rating scale (HAMD) at baseline = 15, be 50 to 80 years old and currently have a BP >140/90 mmHg (threshold recommended by NICE for treatment if 10 year cardiovascular risk > 20% or symptomatic vascular disease).

1. Aged 50-80 (to minimise risk of including people with dementia or pre-dementia)
2. DSM-IV defined MDD will be assessed using SCID by trained staff. Study subjects will have a history of MDD and have current clinically important depressive symptoms (HAMD>15); they will not therefore be in remission and so will have scope for significant improvement in the trial. We will recruit subjects stable on single antidepressant therapy after at least 2 months at a standard dose. As in other depression studies the HAMD will be used for defining the study population but not as an outcome measure. The primary outcome measure will be the Montgomery Asberg Depression Rating Scale.
3. All subjects will have hypertension, defined as having a BP>140/90mmHg recorded as the average of the second and third of three seated BP measurements taken in the left arm at 5 minute intervals. Patients with treated hypertension may enter the study if they are taking only one BP lowering drug and their BP is >140/90mmHg.
4. MMSE >23
5. Medically stable (including no change in medication in the last month)
6. Patient has provided written informed consent for participation in the study prior to any site

specific procedures
7. Male or female participants

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 66

Key exclusion criteria
1. Any other DSM-IV Axis I disorder other than an anxiety disorder unless the depressive episode is considered to be secondary to the anxiety disorder, confirmed using the Structured Clinical Interview for DSM (SCID)
2. Dependence or harmful use of alcohol or other drug in the past 12 months
3. Taking two or more antihypertensive drugs
4. Clinical evidence of dementia
5. History or evidence from neurological examination of clinical stroke
6. History of bipolar or psychotic disorder
7. Severe renal or hepatic impairment
8. Pregnancy or planning to become pregnant within next 12 months or breast feeding
9. Use of other investigational study drugs within 30 days prior to study entry (defined as date of randomisation into study)
10. Previous participation in this study
11. Presence of cardiac pacemaker or other contraindications to MRI

Date of first enrolment
01/02/2012

Date of final enrolment
29/08/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle University
Newcastle Upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Gateshead Health NHS Foundation Trust (UK)

Sponsor details
Queen Elizabeth Hospital
Sheriff Hill
Gateshead
England
United Kingdom
NE9 6SX

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/01aye5y64

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council [MRC] (UK) ref: MR/J011835/1

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/12/2015		Yes	No