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Vascular Augmentation of Late-life Unremitted Depression

Submission date
31/01/2012

Recruitment status
No longer recruiting

Registration date
31/01/2012

Overall study status
Completed

Last Edited
29/08/2019

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Depression in older people is common and leads to other problems. Two thirds of these patients will not have an improvement from routine treatment. About half have a form of depression known as vascular depression. Augmentation - in this case the addition to antidepressant treatment of a vascular type of treatment (such as a group of a medications called Calcium Channel Blockers including the medication called amlodipine) - may work but previously published studies have been from highly selected patient groups. We would like to find out if giving amlodipine medication to people with a late-life non-responding vascular type of depression would be acceptable to this patient group. We would also like to know how they feel while having the treatment , whether this provides a measureable benefit for those patients and whether those benefits are relevant to the patients. We would also like to find out the information we need to plan and prepare for a larger version of this study.

Who can participate?
Participants who 50 years old or over and have been diagnosed with depression which has not improved with other drugs. We call this type of depression vascular depression.

What does the study involve?
If a participant would like to be involved in this study, they would be required to attend the Clinical Ageing Research Unit (CARU) at the former Newcastle General Hospital site in Newcastle upon Tyne (UK) for up to seven visits. They would be required to take the study medication prescribed to them. The study medication may be either amlodipine or placebo. Neither the participant nor the doctor or nurses involved in the study will be aware of which medication has been given (this is called a double blind study, and is done to ensure that there is no other influence on the results apart from the effects of the drug itself). Each participant will be randomly allocated to receiving either amlodipine or placebo (process called randomisation).
At the first visit, participants will discuss the study in further detail and will have the opportunity to ask any questions. If they would like to be involved, they will be invited to return for a second visit at which time they will be asked to give their consent to be involved in the study. They will then need to have their blood pressure taken, have an ECG (electrocardiograph) to establish how well their heart is working, have a small blood sample taken and complete four short questionnaires.

Following on from this, the participant will be invited back for a second visit, which will also be used to confirm the participants eligibility. The participant will be required to have a physical examination, have their blood pressure checked and complete nine short questionnaires.
Once a participant has been confirmed as eligible for the study, they will be entered into the study and randomly allocated to either amlodipine or placebo. The participant will then receive four weeks supply of the study medication.
Two weeks after the second visit, and again at 6 and 12 weeks into the study, each participant will be contacted by the study research nurses in order to review how the participant has been since their last visit.
At weeks 4 and 8 of the study, participants will be required to attend the research centre for another visit, at which point they will be asked to complete two short questionnaires, have their blood pressure taken and current medication reviewed and they will receive their next supply of study medication.
At 16 weeks after starting the study, the study medication will be stopped and participants will be asked to attend another visit at which time current medication will be reviewed, blood pressure will be taken, as well as a blood sample, and participants will also be asked to complete eight short questionnaires. Depending on the results of these questionnaires, participants may be asked to attend for another visit a week later at which point their blood pressure will be taken and they will be asked to complete six short questionnaires.
At 20 weeks after the start of the study, patients will be asked to return for a final visit at which point they will be asked to complete two short questionnaires and have their blood pressure taken once more.
Following on from this study, participants will be returned to the care of their GP.
As part of this study, participants will also be invited to take part in an interview, which will involve the discussion of the various questionnaires undertaken in the study and any other concerns the participant may have had during the course of the study. These interviews will be optional and not be a required part of the study, should the participant decline to take part in the interviews they will still be able to remain on the main part of the study.

What are the possible benefits and risks of participating?
There is no guarantee that taking part in this study may benefit the participant, however it is anticipated that the active medication could reduce the symptoms of their depression. The risk involved in participating in this study is very small, and may include bruising or infection at the site of where the blood samples were taken. Other risks include the possible side effects of the study drug (amlodipine) which may include swelling of the ankles, dizziness, fatigue, nausea, indigestion, palipitations or headaches. These, and other side effects, are listed in the Patient Information Sheet which will be given to each potential participant for further information.

Where is the study run from?
Clinical Ageing Research Unit (CARU) at the former Newcastle General Hospital (UK).

When is the study starting and how long is it expected to run for?
The study will start around March 2013, and will run for approximately 24 months.

Who is funding the study?
The study is sponsored by Gateshead Health NHS Foundation Trust and is funded by National Institute for Health Reseach Research for Patient Benefit (UK).

Who is the main contact?
Julie Henry (Research Nurse) based at the Clinical Ageing Research Unit, Campus for Ageing and Vitality, Newcastle upon Tyne, NE4 5PL, UK, Telephone: +44 191 248 1280 (reception)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2010-023969-21

IRAS number

ClinicalTrials.gov number
NCT01557153

Secondary identifying numbers
10869

Study information

Scientific Title
Vascular Augmentation of Late-life Unremitted Depression: a randomised study

Acronym
VALUeD

Study objectives
Study aims:
1. To find out if giving amlodipine medication to people with a late life non-responding vascular type depression would be acceptable to this patient group
2. To assess how these patients feel while having the treatment and whether this provides a measureable benefit for those patients and whether those benefits are relevant to the patients
3. To find out the information we need to plan and prepare for a larger version of this study

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West- Haydock Research Ethics Committee, 28/10/2011, ref: 11/NW/0551

Study design
Randomised; Interventional; Design type: Treatment

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
Topic: Mental Health Research Network, Primary Care Research Network for England; Subtopic: Depression, Not Assigned; Disease: Depression, All Diseases

Interventions
Study medication, Patients will be randomised to receive either amlodipine or placebo, and will be advised to take 5mg/day for the first four weeks, then up to a maximum dose of 10mg/day for the next 12 weeks. The dose of either can be titrated down to 5mg again if required.; Study Entry : Single Randomisation only

Intervention Type
Drug

Phase
Phase III

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

Primary outcome measure
Reponse rates to study invitation to GP practices and patients; Timepoint(s): For the entire study duration

Secondary outcome measures
1. Blood pressure changes reported; Timepoint(s): at 16 weeks
2. Evaluation of effect on perfusion as determined by second MRI; Timepoint(s): at 16 weeks
3. Measure remission by 16 weeks of augmentation; Timepoint(s): 16 weeks, at end of study
4. Quality of Life questionnaire reporting differences; Timepoint(s): 16 weeks

Overall study start date
01/03/2012

Completion date
02/12/2013

Eligibility

Key inclusion criteria
1. Age 50 years and over
2. Clinically significant (unremitted) vascular depression, as defined above
3. Mini mental state examination (MMSE) >23
4. Medically stable
5. BP < 150/90 (QoF Audit standard)
6. Patient has provided written informed consent for participation in the study prior to any study specific procedures. ; Lower Age Limit 50 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80

Total final enrolment
8

Key exclusion criteria
1. Taking a calcium channel blocker
2. Clinical evidence of dementia
3. History or clinical evidence of stroke
4. History of bipolar or psychotic disorder
5. Significant suicide risk
6. Known hypersensitivity to amlodipine or any other calcium channel blocker
7. Severe renal or hepatic impairment
8. Pregnancy, or women planning to become pregnant within next 12 months, or women who are 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 pace-maker or other contraindications to (only applies to those consenting to MRI sub-study)

Date of first enrolment
01/03/2012

Date of final enrolment
02/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
4th Floor William Leech Building
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

ROR
https://ror.org/01aye5y64

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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?
Basic results			29/08/2019	No	No
HRA research summary			28/06/2023	No	No