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The ReSPonD study - Rivastigmine to Stabilise gait in Parkinsons Disease

Submission date
10/08/2011

Recruitment status
No longer recruiting

Registration date
26/08/2011

Overall study status
Completed

Last Edited
25/01/2016

Condition category
Nervous System Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Falls are common in people with Parkinson's disease (PD). A quarter of people with PD fall at least once a month and they are twice as likely to fall on recurrent occasions compared to older people without PD. The consequences of falls are devastating and costly to the person affected, their carer and society. Falls lead to hospital admission, hip fracture, anxiety and fear of further falls and increase the likelihood of having to live in a nursing home. Apart from the motor features of PD (tremor, stiffness and slowness of movement) impairment in balance is the most common impairment that affects quality of life. Despite the high rate of falls, there are no medical treatments that have been assessed and proven to reduce the risk of falling.
This project aims to discover how well rivastigmine works on correcting the difficulties people with PD have with walking. Rivastigmine is a drug that is licensed for treating memory problems, including memory problems associated with PD. How well it works in improving walking, balance and freezing has not been systematically studied and that is the reason for this study.

Who can participate?
We will recruit 130 men and women with PD, from 18-100 years old, who have had a fall in the past year. A small subset of 5-10 healthy people without PD will be asked to have their walking measured in a laboratory. This will enable us to check the equipment we use and devise suitable tests that people perform whilst they walk.

What does the study involve?
People who take part in the study will be involved for one year. You will take active or placebo (dummy) medication for the first 32 weeks. About half the people who take part will receive the active (real) medication and the other half will receive the placebo (dummy) medication. We will test your walking and balance in detail on two occasions at the start and after 32 weeks. For the remainder of the year you will be asked to record any falls that occur in diaries at home and return these to us each month.

What are the possible benefits and risks in participating?
If you are in the group that receives the active medication capsules your walking unsteadiness and /or balance impairment may improve along with your attention, concentration and memory. You have a 50% chance of being able to access a potentially new and helpful drug to treat

aspects of PD.
You may be reassured and benefit from the frequent visits and follow up. We cannot promise the study will help you but the information we get from this study will improve the treatment of people with PD in the future.
The medication can have side effects. One of the more common side effects is stomach upset (feeling sick, vomiting or having diarrhoea). More information is available about possible side effects and what happens if they occur in the Information Leaflet available from the research team.

Where is the study run from?
The study is run from Frenchay Hospital which is part of North Bristol NHS Trust. Some people who take part may have their Parkinsons disease treated at other hospitals in the area. However, all the assessments in the trial will take place at Frenchay Hospital.

When is the study starting and how long is it expected to run for?
We aim to start recruiting people to take part towards the end of 2011. We will continue to recruit people until we reach 130 participants which is likely to take 12-18 months.

Who is funding the study?
The study is funded by a Parkinson's UK training fellowship award.

Who is the main contact?
Dr Emily Henderson, Emily.Henderson@bris.ac.uk
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1466

Study information

Scientific Title
A phase II, randomised, double blind, placebo controlled trial to evaluate the effect of Rivastigmine on gait in patients with Parkinsons disease who have fallen

Acronym
The ReSPonD Study

Study objectives
Treating people with Parkinsons disease (PD), who have fallen, with rivastigmine will show superiority over placebo by stabilising their gait (reducing gait variability), increasing their balance and confidence and reducing their risk of falling. These changes will be mediated by augmenting cognition and as such the improvement will be more evident whilst walking and performing dual tasks.

Please note that as of 01/10/2012 the anticipated end date for this trial was updated from 01/12/2013 to 30/04/2014

Ethics approval required
Old ethics approval format

Ethics approval(s)
South-West Central Bristol, approval granted 28/09/2011 ref: 11/SW/0234

Study design
Single centre randomised double blind placebo controlled trial

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
Parkinson's disease

Interventions
Active Arm: Exelon® [Rivastigmine] orally. Uptitration (16 weeks): 1.5mg twice a day for four weeks, 3mg twice day for four weeks, 4.5mg twice day for four weeks, 6mg twice day for four weeks. Maintenance (16 weeks) highest tolerated dose.
Placebo arm: Identical matched placebo capsules with dummy uptitration schedule.
Total treatment time 32 weeks.

Intervention Type
Other

Phase
Phase II

Primary outcome measure
Current primary outcome measures as of 01/10/2012
Gait variability (step time variability) with three paradigms:
1.1. Normal walking
1.2. Walking plus verbal fluency
1.3. Walking plus switching
at 32 weeks

Previous primary outcome measures until 01/10/2012:
Gait variability (step time variability) whilst undertaking dual task at 32 weeks

Secondary outcome measures
Current secondary outcome measures as of 01/10/2012:
1. Change in harmonic ratios and other spatio-temporal gait parameters (velocity, cadence, step length (cm), stance time, stance time variability, double limb support (% of gait cycle) walk ratio, under three paradigms:
1.1. Normal walking
1.2. Walking plus verbal fluency
1.3. Walking plus task switching
2. Cognition [verbal fluency performance, Montreal Cognitive Assessment (MOCA), Cognitive Failures Questionnaire (CFQ), Test Your Memory (TYM), frontal assessment battery (FAB)]
3. Falls and resultant injuries (number and rate of falls, proportion of fallers in each group, injuries and healthcare resource use)
4. Falls risk factors (visual contrast sensitivity, lower limb proprioception and strength, reaction time, postural sway)
5. Parkinsons Disease Falls Risk Score
6. Balance in standing (coordinated stability)
7. Fear of falling (Icon-FES)
8. Freezing (FOG questionnaire, and quantification from FOG walking paradigm)
9. Mood (15 item Geriatric Depression Score)
10. Parkinsons disease symptoms and stage Unified Parkinson's Disease Rating Scale (UPDRS)
11. Quality of life (EQ-5D)
12. Adverse events

Previous secondary outcome measures until 01/10/2012:
1. Change in other spatio-temporal gait parameters (velocity, cadence, step length (cm), stance time, stance time variability, double limb support (% of gait cycle) under three paradigms:
1.1. Normal walking

1.2. Walking plus verbal fluency
1.3. Walking plus task switching
8. Freezing (FOG questionnaire, and objective quantification)

Overall study start date
01/12/2011

Completion date
30/04/2014

Eligibility

Key inclusion criteria
1. Patients with moderate (Hoehn and Yahr stage 2-3) PD.
2. History of having fallen at least once in the last year
3. Participants must be able to walk, without aids, for the length of the walking protocol (approximately 18m)
4. Stable on anti-Parkinsonian medication for 2 weeks prior to enrolment
5. Able to give informed consent and willing to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 130; UK sample size: 130

Key exclusion criteria
1. Patients with any other cause [vascular, multisystem atrophy (MSA), progressive supranuclear palsy (PSP), normal pressure hydrocephalus) of Parkinsonism
2. Known diagnosis of dementia
3. Patients with other neurological, visual or orthopaedic problems that significantly interfere with balance or gait
4. Previous or current treatment with a cholinesterase inhibitor or absolute contraindication to cholinesterase inhibitor therapy
5. Inability to attend or comply with treatment or follow-up scheduling
6. Non-English speaking patients, as cognitive tests will be performed in English

Date of first enrolment
01/12/2011

Date of final enrolment

30/04/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Bristol NHS Trust
Bristol
United Kingdom
BS16 1JE

Sponsor information

Organisation
University of Bristol (UK)

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Sponsor type
University/education

Website
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ROR
https://ror.org/0524sp257

Funder(s)

Funder type

Research organisation

Funder Name
Parkinson's UK Career Development Award (UK)

Funder Name
British Geriatrics Society (UK) - Start-up grant

Funder Name
North Bristol NHS Trust (UK) - Small grant scheme

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?
Protocol article	protocol	03/12/2013		Yes	No
Results article	results	01/03/2016		Yes	No
HRA research summary			28/06/2023	No	No