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A phase IV acceptability and feasibility trial of the effects of medication on memory in idiopathic nondementing Parkinson's disease

Submission date	Recruitment status	[ ] Prospectively registered
12/06/2013	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/06/2013	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/06/2019	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2012-000801-64

Protocol serial number
13793

Study information

Scientific Title
A phase IV acceptability and feasibility trial of the effects of medication on memory in idiopathic nondementing Parkinson's disease

Acronym
MeMory PaD

Study objectives
An estimated 122,795 people aged 65+ in the UK have Parkinson's disease (PD). Its a progressive illness caused by the loss of a brain chemical called dopamine which results in tremor, slowed movement and difficulty initiating voluntary movements. Dopamine restoring drugs provide respite from these symptoms with slow-release dopamine agonists (ropinirole hydrochloride prolonged release and pramipexole dihydrochloride monohydrate prolonged release) being the mainstay of treatment. PD patients also report memory decline, the severity of which is reduced when they wake up in the morning before they take their dopamine-replacement medication as compared to the rest of the day implying that the same medication which offers relief from movement problems simultaneously impairs memory. In a series of studies memory was assessed before and after PD patients had taken their morning medication. The findings showed a significant decline in memory when patients were medicated compared to un-medicated. This effect was particularly marked for patients on dopamine agonists (ropinirole hydrochloride prolonged release and pramipexole dihydrochloride monohydrate prolonged release) compared to a different class of dopamine-restoring medication (i.e. l-dopa).These findings are important because patients are not seeking help for their memory decline and clinicians are not providing advice to patients about this or considering memory decline when making treatment choices. The over-arching aim of this research programme is to release a set of guidelines of the causes and management of drug-dependent memory decline for clinicians (target 2017) with the purpose of increasing general awareness of memory decline in PD. This feasibility trial represents the 1st stage in this programme, its purpose to gather info about a series of process outcomes such as drop-out rate and to identify barriers to participation, all of which will feed into a larger multi-centre randomised controlled trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/NW/0009

Study design
Non-randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Dementias and Neurodegenerative Diseases Research Network; Subtopic: Parkinson's Disease; Disease: Parkinson's disease

Interventions

Cross over trial. In arm 1, patients-participants start on pramipexole and then switch to ropinirole. In arm 2, they start on ropinirole and are then switched to pramipexole. Patient-participants are stabilised on each medication for 6 weeks before having their memory assessed twice when in a medicated state and following a period of medication withdrawal (termed ON and OFF state)

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Pramipexole, Ropinirole

Primary outcome(s)
Estimates of memory performance which will inform a power calculation for a large RCT; Timepoint(s): Baseline, 2 memory assessments : mid study and end of study

Key secondary outcome(s))
Efficacy of processes and procedures used during the medication withdrawal process; Timepoint (s): mid study, end of study

Completion date
04/02/2015

Eligibility

Key inclusion criteria
Demographic characteristics:
1. Males and females
2. Aged between 50-80 years

Medical condition:
1. Idiopathic, sporadic Parkinsons disease, diagnosed by as determined by the UK Parkinsons Disease Society Brain Bank Clinical Diagnostic Criteria (1992) Parkinsons disease stages, mild: 1, 2, 2.5; or moderate: 3 and 4, as determined by the modified Hoehn-Yahr (HY) disease severity rating scale
2. Capacity to provide fully informed signed consent

Indicated treatments:
1. Currently medicated with slow release preparations of either pramipexole ER or ropinirole XL
2. Adjuvant therapy with ldopa and/or a monoamine oxidase B inhibitor (such as rasagiline /AZILECT or selegiline/ ELDEPRYL, ZELAPAR)

Target Gender: Male & Female; Upper Age Limit 80 years ; Lower Age Limit 50 years

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Senior

Sex
All

Total final enrolment
22

Key exclusion criteria
Demographic characteristics:
1. Patient-participants younger than 50 and older than 80 years of age
2. English is a second language

Medical, psychiatric, developmental conditions:
1. Cognitive impairment as assessed with the Mini-Mental State Examination scoring of 25 or less
2. Familial Parkinson's disease
3. Severe Parkinson's disease, indicated by a score of 5 on the Hoehn and Yahr disease severity rating scale
4. Unable to provide informed consent due to cognitive decline
5. Comorbid for another neurological illness (other than Parkinsons disease)
6. History of learning difficulty including dyslexia
7. Physical inability to attend or comply with treatment scheduling, such as upper limb amputations, Crippling degenerative arthritis
8. Current or planned participation in another clinical trial or study
9. Active malignancy
10. Pre-planned or elective surgeries during the period of involvement in the trial
11. Prior or current history (within the previous 5 years) of significant and/or uncontrolled drug abuse or alcoholism
12. Major psychotic phenomenology including hallucinations or lack of awareness of dyskinesias
13. Hypotension: severe dizziness or fainting on standing
14. Impulse control disorders or compulsive behaviours
15. Incapacitating dyskinesias on a stable dose of ldopa
16. Hepatic impairment
17. Severe renal impairment (creatinine clearance < 50 ml/min)
18. eGFR of less than 50 ml/min/1.73m(squared)
19. Women of child bearing potential unless they are using a recognized, effective form of contraception or they are not sexually active and have no intention of becoming sexually active during the duration of their involvement in the trial
20. Contraindicated treatments
21. Patient-participants taking any of the following drugs:
21.1. COMT inhibitors (entacapone/COMTAN or tocapone/TASMAR)
21.2. Apomorphine
21.3. Amantadine (population pharmacokinetic analyses suggest that amantadine may slightly decrease the oral clearance of pramipexole)
21.4. Anticholinergics
21.5. Dopamine antagonists (phenothiazines, butyrophenones, thioxanthenes) or

metoclopramide, ciprofloxacin
21.6. Immediate-release preparations of either pramipexole or ropinirole
22. Patient- participants treated with deep brain stimulation

Date of first enrolment
04/02/2013

Date of final enrolment
04/02/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Neurology Research Unit
Stoke-On-Trent
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Sponsor information

Organisation
University Hospital of North Staffordshire (UK)

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research - Research for Patient Benefit (RfPB); Grant Codes: PB-PG-0211-24101

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

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			21/06/2019	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes