NCT06192823

Feasibility Of Objective Measures and Outpatient Washout in Disease Modifying Trials for Parkinson's Disease

06/12/2024

VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Feasibility of Objective Measures and Outpatient Washout in Disease-Modifying Trials for Parkinson's Disease
Version Date:	June 29, 2022
PI:	Mallory Hacker, PhD, MSCI

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key information about this study:

You are being asked to take part in this research study because you have early-stage Parkinson's disease (PD) and have done well on standard medical treatment.

The purpose of this study is to test new study procedures as part of a 7-day period where PD patients do not take any of their PD medications ("washout"). The new study procedures include brain scans and wearable movement trackers, in addition to PD rating scales, patient questionnaires, and cognitive testing.

The goal of this study is to determine whether to include these new study procedures in future clinical trials that will test whether a treatment slows the progression of PD.

What will happen and how long will you be in the study?

The study consists of a screening visit that will last approximately half a day, a medication optimization visit which may occur in person or via telehealth, and a study visit that will last 8 days. You will be provided lodging at a hotel near Vanderbilt for the duration of the study visit (8 nights) at no cost to you.

All tests are for research purposes and will be done at Vanderbilt University Medical Center.

Prior to your screening visit, you will be asked to stop taking your PD medication so the researchers can accurately evaluate your PD symptoms while you are off of your medications. After testing has been done while you are off of your medications, you will be asked to take your morning dose of PD medication.

During the screening visit, your motor symptoms will be evaluated while you are off your medications and again after you take your first morning dose. Other inclusion and exclusion criteria will be reviewed as well at the screening visit.

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Within two weeks of completing the screening visit, you will be seen by the treating neurologist to optimize PD medications so that the test results obtained at the 8-day study visit reflects true ON medication states. This visit may be conducted in-person or via telehealth. Prior to the 8-day study visit, you will be asked to wear a device similar to a wristwatch (the Parkinson's KinetiGraph™, PKG™) that measures your Parkinson's disease symptoms. This device will be worn for 6 days before you arrive.

Each day of the study visit, you will come to the Clinical Research Center (CRC) on the Vanderbilt campus to complete study assessments. Free shuttle service is provided by the hotel.

During your 8 days of study assessments, the following will be done:

- Complete surveys about your symptoms.
- Videotape your Parkinson's exam to record your motor function while on your regular medications (Day 1)
- The afternoon of your first full day (Day 1), you will stop taking your Parkinson's medication ("washout"). Your tremor, stiffness, slowness, and gait will be rated and videotaped each morning in the CRC for one week (Day 2 – 8).
- A series of neuropsychological tests to check your memory, attention, and problem-solving skills.
- Your blood pressure and heart rate will be measured while you are sitting and standing.
- On the first and last days, you will undergo PET/CT scans of your head. This procedure will be described in more detail throughout this document.

While at the hotel, you will eat your normal diet and will not have to change your daily routine. After you complete the last study visit at the CRC (Day 8), you will resume your regular Parkinson's medications.

You can withdraw from the study and resume your Parkinson's medications at any time.

A neurologist specializing in movement disorders (Dr. David Charles) will perform the following tests while you are in the CRC:

- History and physical exam
- Movement Disorders Society Unified Parkinson's Disease Rating Scale (MDS-UPDRS)
- Unified Dyskinesia Rating scale
- Hoehn & Yahr (scale of severity of your PD)

- Schwab & England (scale of your degree of functional independence)

The Study Coordinator will perform the following tests while you are in the CRC:

- Review of your medications
- Review of any medical problems you may have had
- Videotape of your MDS-UPDRS-III in both ON and OFF states (evaluation of your motor skills)
- Stand Walk Sit Test (you will stand, walk 20 feet, turn and return to starting point)
- Finger Tap Test (you will tap a mechanical counter with your index finger for 30 seconds as fast as you can). You will use your left and right hands.
- Global Assessment Form (table with scores for activity rated by you)
- Kinesia One™ task-based motor assessments. Kinesia One™ is another type of wearable device that will let researchers measure your Parkinson's disease symptoms.
- King's Pain PD Quest

A research coordinator that has been trained by a neuropsychologist (Dr. Ciaran Considine) will administer the cognitive testing to evaluate the following:

- Attention
- Memory
- Visual processing
- Speech
- Language
- Motor skills
- Intelligence

In addition, you will complete a quality of life questionnaire (PDQ-39).

You will be asked to fast (not eat) overnight before coming in for the first day. On the first day, while you are still on your Parkinson's medications, you will undergo a PET/CT scan. The PET session will take approximately 1.5 hours. PET scans are used to make images that detect gamma rays (a kind of radiation) using rings of sensors that are placed around the head. This is similar to x-rays, except that instead of having a radiation source outside of your body (as in x-rays), a chemical that makes gamma rays is injected into your bloodstream. The chemical compound injected in this study is called [^{18}F]-fluorodeoxyglucose, or FDG for short. FDG is a radioactive compound because the [^{18}F] part of the compound breaks down quickly, making gamma rays that can be measured

with the PET scanner. FDG PET is widely used to study regional brain metabolism (energy usage) and has been approved by the Food and Drug Administration for both research and clinical use. FDG is made on site at Vanderbilt following strict procedures to assure that the FDG is produced properly.

When you come to the PET scan session, an IV will be placed in either one of your arms. The FDG will be administered, and you will be asked to relax in a darkened room with your eyes closed for between 15 and 30 minutes. You will then be taken across the hall to the PET scanner, and you will be asked to lie still within the PET scanner for up to 35 minutes. Your head will be stabilized to minimize movement during the PET scan. The PET scanner will take a picture of the thickness of your skull (called an attenuation CT scan), as well as a picture of the amount of metabolism in the different parts of your brain.

After fasting overnight, on Day 8 the motor assessment will be videotaped, and you will undergo one more PET/CT scan. Procedures for this scan will be identical to the scan conducted on the first day.

Table 1: Study Procedures

Procedure	Administrator	Approximate Time	Mode of Administration
History and Physical	Dr. Charles	45 mins	One-on-one
Medication Log	Study Coordinator	10 mins	One-on-one
Adverse Events Log	Study Coordinator	10 mins	One-on-one
Neuropsychological Testing	Study Coordinator	90 minutes	One-on-one
MDS-UPDRS and UPDRS	Dr. Charles, Study Coordinator	20 mins	One-on-one
Dyskinesia Rating	Study Coordinator	5 mins	One-on-one
Hoehn & Yahr	Dr. Charles	1 min	One-on-one
Schwab & England	Dr. Charles	2 mins	One-on-one
Stand Walk Sit Test	Study Coordinator	5 mins	One-on-one
Finger Tap Test	Study Coordinator	5 mins	One-on-one
Patient Global Assessment	Study Coordinator	2 mins	One-on-one
King's Pain PD Quest	Study Coordinator	2 mins	One-on-one
PET scan	Dept. of Radiology	90 minutes (First Day) 90 minutes (Day 8)	
Kinesia One™ Task-Based Assessments	Study Coordinator	20 mins	One-on-one

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Table 2: Washout Assessment Procedures

Evaluation/Procedure	Day of Assessment									
	SV	0/1	2	3	4	5	6	7	8	Early Exit
Informed Consent	X									
History and *, Medication Review*	X	X								
Physical and Neurologic Examination*	X	X							X	X
Investigator Wellness Check*			X	X	X	X	X	X		X
Neuropsychological Screening~	X									
Inclusion/Exclusion Criteria Review*, ^	X									
Adverse Event Review^		X	X	X	X	X	X	X	X	X
Autonomic Testing#		X	X	X	X	X	X	X	X	X
Neuropsychological Test Battery~		X						X		
PDQ-39+		X								
MDS-UPDRS & UPDRS Parts I, II, IV*		X								
MDS-UPDRS & UPDRS Part III (videotaped)^		X							X	X
Kinesia ONE Motor tasks^		X	X	X	X	X	X	X	X	X
Hoehn & Yahr*		X							X	X
Schwab & England*		X							X	X
Timed Tests (stand/walk/sit, finger taps)^		X							X	X
Unified Dyskinesia Rating Scale (videotaped)^		X								
Clinician Global Impression of Severity (CGI-S)*		X							X	X
Clinician Global Impression of Change (CGI-C)*									X	X
Patient Global Impression of Severity (PGI-S)+		X							X	X
Patient Global Impression of Change (PGI-C)+									X	X

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Quality of Life in Essential Tremor (QUEST)+		X							X	
EQ-5D-5L+		X							X	
Pain Assessment+	X	X	X	X	X	X	X	X	X	X
King's PD Pain Scale+		X							X	
Columbia Suicide Severity Rating Scale~	X	X								
PET/CT Scan		X							X	

SV = Screening Visit
*Performed by the study neurologist.
~Performed by a research assistant trained by neuropsychologist to complete the neuropsychological assessments.
+ Completed by patient via self-report (guided by the study coordinator)
^Collected by the study coordinator
#Collected by CRC staff

About 2-4 weeks after you complete your visit at Vanderbilt, you will be asked to complete a phone interview to understand what your experience was like while participating in the study. This interview will take approximately 1 hour.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Side effects and risks that you can expect if you take part in this study:

You may be inconvenienced by staying at a hotel for 8 nights and completing the daily study assessments. You may ask to stop and rest at any time during the testing. You also have the option of not completing the testing. This study requires that you temporarily stop a dopaminergic medication, and, therefore, there is a potential risk of dopaminergic withdrawal, a rare, potentially life-threatening condition characterized by altered mental status, fever, rigidity, and autonomic instability (change in blood pressure and heart rate). You will stop your Parkinson's medicine on the first day for this study.

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Risks of Radiation:

This research study may involve exposure to radiation from up to 2 CT Attenuation Scans and 2 FDG PET scans. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation that you may receive by participating in this study is e qual to your body receiving 59 month (4.9 years) or radiation from your natural surroundings or about 30% of the amount allowed in a year for people who are exposed to radiation as part of their work. To protect your bladder from the effect of the injected radioactive substances. You should drink plenty of fluids and empty your bladder every two hours for at least the first six hours after you have each PET/CT scan.

Risks that are not known:

The tests and procedures that you are required to perform in this study may involve direct risks to you that at the present time are not known.

During the study, if any new facts become known about added risks and side effects, the study doctor will tell you, and further treatment will be discussed. You will receive information about any new findings that may change your mind about staying in the study.

Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study are that this study will improve our understanding of how patients with early stage PD who have been off of PD medications for 7 days are able to tolerate getting PET scans and using wearable movement trackers. This information will help researchers decide whether to include these study procedures in future Parkinson's disease clinical trials.

b) The benefits you might get from being in this study: You will not receive any direct benefit for taking part in this study.

Procedures to be followed:

During your screening visit, you will complete the following to ensure you meet the inclusion and exclusion criteria:

- Arrive off PD medication

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- UPDRS-III off evaluation
- Take first morning dose of PD medication
- UPDRS-III on evaluation
- Neurological examination
- Inclusion/exclusion criteria review
- Neuropsychological screening assessment

The study neurologist will meet with you to evaluate the medications you take for PD and try to optimize them, if needed.

You will be asked to wear a movement tracker similar to a wrist watch for 6 days prior to coming to Vanderbilt.

During your 8 days of study assessments, the following will be done:

- Complete surveys about your symptoms.
- Videotape your Parkinson's exam to record your motor function while on your regular medications (Day 1)
- The afternoon of your first full day (Day 1), you will stop taking your Parkinson's medication ("washout"). You will complete motor-related tasks using a wearable sensor each morning in the CRC for one week (Day 2 – 8).
- A series of neuropsychological tests to check your memory, attention, and problem-solving skills will be given on Day 1 and Day 7.
- Your blood pressure and heart rate will be measured while you are sitting and standing.
- On the first and last days, you will undergo PET/CT scans of your head. This procedure will be described in more detail throughout this document.

You will be interviewed by phone approximately 2-4 weeks after completing the study and be asked about what it was like to be part of the study.

Payments for your time spent taking part in this study or expenses:

You will receive $155 for travel. You will receive $50 for the screening visit. You will receive $30 for each day you complete the assessments at the CRC. You will receive $20 for wearing the Parkinson's wristwatch for 6 days prior to coming to Vanderbilt. You will receive $20 for completing the follow-up phone call interview. You will receive up to a total of $485 for participating in the study.

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You will be reimbursed up to $60 per day for your meal expenses while participating in the study.

We may ask for your social security number and address before you are compensated for taking part in this study.

Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact David Charles, M.D. at (615) 322-2538 or Mallory Hacker, Ph.D., M.S.C.I., at (615) 875-7437. If you cannot reach the research staff, please page the study doctor at (615) 835-8141.

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For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:

You may be asked to leave the study if you cannot complete all the study procedures or if you cannot come to Vanderbilt for the tests. If you are taken out of the study, you will be told the reason why.

What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor.

Confidentiality:

The information we collect about you will be recorded on paper forms. The forms will be labeled with a code that will not identify you. The forms will be kept in a locked room in the study coordinator's office when not in use. The key to the codes will be kept in a locked box. Only the investigator and her research staff will have access to the key for the codes and the information we collect about you.

The videotapes and audiotapes will also be stored in a locked box in the study coordinator's room that is locked when not in use. Only the investigator and her research staff will have access to the tapes. The videotapes will be labeled with a code that will not identify you. At the conclusion of the study, videotapes will also be accessed by a movement disorders expert who will review and score each visit.

The videotapes and data will be kept for at least six years after the study is finished. At that time the research data and videotapes collected during the study will be screened for medical significance. The documents not already in your medical record and are deemed irrelevant to your ongoing medical treatment (including the videotapes), will be destroyed immediately. Any research information entered into your medical record will be kept indefinitely.

Vanderbilt may share your health data, without identifiers, to others or use it for other research projects not listed in this form. Dr. Hacker and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

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Your personal information will be disclosed to Global Kinetics Corporation (GKC), manufacturers of the PKG™ system, in order for GKC to assist you in setting up the wearing of the PKG™ device.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Hacker in writing and let her know that you withdraw your consent. Her mailing address is 1161 21st Avenue South, Medical Center North, Suite A-1106, Nashville, TN 37232. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

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Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive, or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

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What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____

Date Signature of patient/volunteer

Consent obtained by:

_____ _____

Date Signature

_____

Printed Name and Title

Time: _____