Adaptive DBS Algorithm for Personalized Therapy in Parkinson*s Disease (ADAPT-PD) Trial

Published: 26-02-2021
Last updated: 05-10-2024

The purpose of the study is to demonstrate the safety and effectiveness of adaptive DBS (aDBS) for Parkinson*s disease.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON54430

Source
ToetsingOnline

Brief title
ADAPT-PD Trial

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic Trading NL BV
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: Adaptive DBS, aDBS, DBS, Deep Brain Stimulation, Parkinson's Disease, PD

Outcome measures

Primary outcome

To demonstrate that the proportion of aDBS subjects with *On* time without troublesome dyskinesia during the Evaluation Phase exceeds a performance goal of 50%.

Secondary outcome

To demonstrate decreased stimulation energy use during the aDBS Evaluation Phase as compared with cDBS.

Study description

Background summary

Please see CIP version 5.0 page 26 section 3.1.

Study objective

The purpose of the study is to demonstrate the safety and effectiveness of adaptive DBS (aDBS) for Parkinson*s disease.

Study design

Prospective, single-blind, randomized crossover, multi-center study of aDBS in subjects with Parkinson*s disease.
The study is expected to be conducted at approximately 12 centers located in the US, Europe and Canada. It is estimated that approximately 70-100 subjects implanted with a commercially available Medtronic DBS system with Percept PC INS will be enrolled to obtain 40 subjects for whom at least 1 aDBS mode is acceptable and who enter the aDBS evaluation phase. Accounting for a 10% dropout during the aDBS Evaluation Phase, a minimum of 36 subjects (at least 8 per brain target) will complete the aDBS Evaluation phase.
In addition, approximately 15 subjects implanted with a commercially available Medtronic DBS system with Percept PC INS and SenSight system will be enrolled

in the Directional Stimulation Cohort to obtain 9 subjects for whom at least 1 aDBS mode is acceptable and who enter the aDBS Evaluation Phase. Accounting for dropout during the aDBS Evaluation Phase, a minimum of 8 subjects will complete the aDBS Evaluation Phase.
Study visits and/or phases include:
• Enrollment Visit: Consent, Screening
• cDBS Baseline Phase: Local Field Potential (LFP) Screening and Baseline cDBS visits
• aDBS Setup and Adjustment Phase: aDBS Setup visit and additional optional visits during an aDBS Adjustment period
• aDBS Evaluation Phase: One-month treatment periods in each acceptable aDBS mode with aDBS evaluation visits at the end of each period. Randomized crossover to the two investigational treatments in subjects for whom both aDBS modes were acceptable and a single treatment period in those subjects for whom only one aDBS mode was acceptable.
• Long-Term Follow Up Phase: Four visits in preferred aDBS mode for approximately 10 months
• Extended Access Phase: Additional visits in the preferred aDBS mode every 6 months through commercial approval of aDBS

Intervention

Please see section 9.3 of CIP version 3.0

Subjects will be considered enrolled at the time they sign the informed consent form.
Scheduled visits will include the following:
Enrollment, LFP Screening, cDBS Baseline, aDBS Setup, Randomization, aDBS Evaluation Visit 1, aDBS Evaluation Visit 2, Long-term follow-up Visit 3, Long-term follow-up Visit 4, Long-term follow-up Visit 5, and Long-term follow-up Visit 6. Extended Access Visits Every 180 +/- 60 days beginning after Visit 6 and every 6 months thereafter following the previous extended access visit
Subjects participating in the extended access phase prior to commercial approval of aDBS, will have visits every 6 months.
The following assessments / data will be collected during the study:
• Concomitant medications
• PDQ-39
• EQ-5D-5L
• MDS-UPRDS Parts I-IV
• Parkinson*s Disease Home Diary
• VHI
• PDSS-2
• aDBS Global Impression of Change score
• Patient preference questionnaire
• Patient satisfaction questionnaire
• Wearable data

• Programming session data, including BrainSense data
• Event markers (optional)
• Adverse Events and Device Deficiencies

Study burden and risks

The benefit of the study lies in the knowledge to be gained from the results and the potential to improve future DBS therapies. All the potential risks have been controlled to a level as far as possible. Based on the risk acceptance criteria for the ADAPT-PD Trial laid out in the Study Risk Management Plan, the study-specific residual risk is determined to be acceptable given the expected benefits.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion Criteria:
General (Primary Cohort):
1. Subject has idiopathic Parkinson*s disease
2. Subject is implanted with Percept PC (Model B35200) and Medtronic DBS leads (Model 3387, 3389, B33005 or B33015) and extensions (Model 37085, 37086 or B34000) bilaterally in the same target (physician confirmed), STN or GPi
3. In the opinion of the investigator, the subject responds to DBS Therapy.
4. Based on the opinion of the investigator, the subject*s cDBS parameters and PD medications are stable and expected to remain stable from enrollment through the end of the aDBS Evaluation phase
5. Subject is configured to ringmode monopolar or dual monopolar stimulation using contacts 1 and/or 2 (9 and/or 10) on at least one side.
6. Subject is willing and able to attend all study-required visits and complete the study procedures (e.g. 1-month recall questionnaires, MDS-UPDRS III)
7. Subject has the ability to understand and provide written informed consent for participation in the study prior to the study-related procedures being conducted
8. Subject is a male or non-pregnant female. If female of child-bearing potential, and if sexually active, must be using, or agree to use, a medically-acceptable method of birth control as confirmed by the investigator
9. For subjects with the SenSight system: Subject is configured to the following stimulation rates: 55, 85, 110, 125, 145, 164 or 180 Hz (as required for sensing/aDBS)

General (Directional Stimulation Cohort):
Subjects must meet the same inclusion criteria as the primary cohort except for revised #2 and #5.
Revised Inclusion Criteria:
2. Subject is implanted with Percept PC (Model B35200) and Medtronic DBS leads (Model B33005 or B33015) and extensions (Model B34000) bilaterally in the same target (physician confirmed), STN or GPi
5. Subject is configured to directional monopolar or dual monopolar stimulation using contacts 1 and/or 2 (9 and/or 10) .

LFP Screening
Inclusion Criteria (All Cohorts):
1. Subject has Alpha-Beta band (8-30 Hz) amplitude >= 1.2 µVp detected on either left and/or right DBS leads on sensing channels 0-2, 0-3, or 1-3; 8-10, 8-11, or 9-11

Exclusion criteria

Exclusion Criteria (All Cohorts)
1. Subject and/or caregiver is unable to utilize the patient programmer
2. Subject has more than one lead in each hemisphere of the brain
3. Subject has cortical leads or additional unapproved hardware implanted in the brain
4. Subject has more than one INS
5. At enrollment, the subject*s INS has a predicted battery life of <1 year
6. Subject has Beck Depression Inventory II (BDI-II) > 25
7. Subject requires diathermy, transcranial magnetic stimulation (TMS), or electroconvulsive therapy (ECT)
8. Subject has a metallic implant in the head, (eg, aneurysm clip, cochlear implant)
9. Subject has, or plans to obtain, an implanted electrical stimulation medical device anywhere in the body (eg, cardiac pacemaker, defibrillator, spinal cord stimulator)
10. Subject has, or plans to obtain, an implanted medication pump for the treatment of Parkinson*s disease (eg, DUOPATM infusion pump) and/or portable infusion pump
11. Based on the opinion of the investigator, the subject has an abnormal neurological examination that would preclude them from study participation
12. Subject is breast feeding
13. Subject is under the age of 18 years
14. Subject is currently enrolled in or plans to enroll in any concurrent drug and/or device study that may confound the results of this study as determined by the Medtronic study team
15. Subject is unable to use or tolerate wearable
16. Subjects with signal artifact on all 6 aDBS sense pathways (3 each on both DBS leads) which preclude the clinician from setting thresholds

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-06-2021
Enrollment:	13
Type:	Actual

Medical products/devices used

Generic name:	Model B35200 Percept PC INS with aDBS firmware (FW) enabled
Registration:	No

Ethics review

Approved WMO Date:	26-02-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-05-2024
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389

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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT04547712
CCMO	NL74334.018.20