

Summary of Clinical Trial Results

For Laypersons



A study to learn how effective and safe a medicine containing levodopa-carbidopa is compared to current standard patient medication to treat dyskinesia in adult patients with advanced idiopathic Parkinson's disease

Overall Summary

- Researchers are looking for a better way to treat advanced Parkinson's disease (PD).
- Researchers in this study wanted to know whether an approved drug, Levodopa-Carbidopa Intestinal Gel (LCIG), could help treat the dyskinesia associated with advanced idiopathic PD.
- This study took place from February 2017 to September 2019 in 7 countries.
- A total of 61 adult patients took part in the study; 7 patients left the study, mostly due to withdrawal of consent.
- The study was divided into 3 parts: Screening Period, Treatment Period, and Follow-Up Period. Patients were randomly (by chance) assigned to treatment groups (current standard treatment or LCIG treatment). Patients assigned to the current standard treatment group continued the same PD treatment they received prior to the study. Patients assigned to the LCIG group switched their previous PD treatment to LCIG.
- This study found that treatment with LCIG significantly decreased dyskinesia compared to current standard treatment in patients with advanced idiopathic PD.
- The beneficial effects of LCIG were seen at 2 weeks and continued throughout the rest of the Treatment Period.
- More patients who received treatment with LCIG experienced side effects compared to patients who received treatment with current standard treatment. Side effects in this patient population were similar to side effects seen with the medical procedures performed in other previous studies amongst patients with PD.
- The results of the study may be used by researchers to further develop this medicine.
- If you participated in this study and have questions about your individual care, contact the doctor or staff at your study site.

1. General information about the study

1.1 What was the main objective of this study?



Researchers are looking for a better way to treat symptoms of advanced PD. Parkinson's disease (PD) is a degenerative disorder, wherein cells in the brain stop working and lose function over time. As a result, patients experience tremors, muscle rigidity, and loss of control of mobility. The study drug used in this study, levodopa-carbidopa, is currently approved by regulatory authorities to treat advanced PD. Due to the chemical nature of levodopa-carbidopa in its oral form, patients with advanced PD sometimes develop levodopa-induced dyskinesia, a condition where involuntary movements occur, even when the patients' medication is otherwise working.

Researchers in this study wanted to know whether a drug, Levodopa-Carbidopa Intestinal Gel (LCIG), a treatment already approved for the treatment of immobility in patients with PD, could help treat the involuntary movements associated with dyskinesia in patients with advanced PD. Unlike the oral version, LCIG is a gel and is delivered to the intestine via a portable pump which provides continuous levodopa-carbidopa, reducing dyskinesia symptoms.

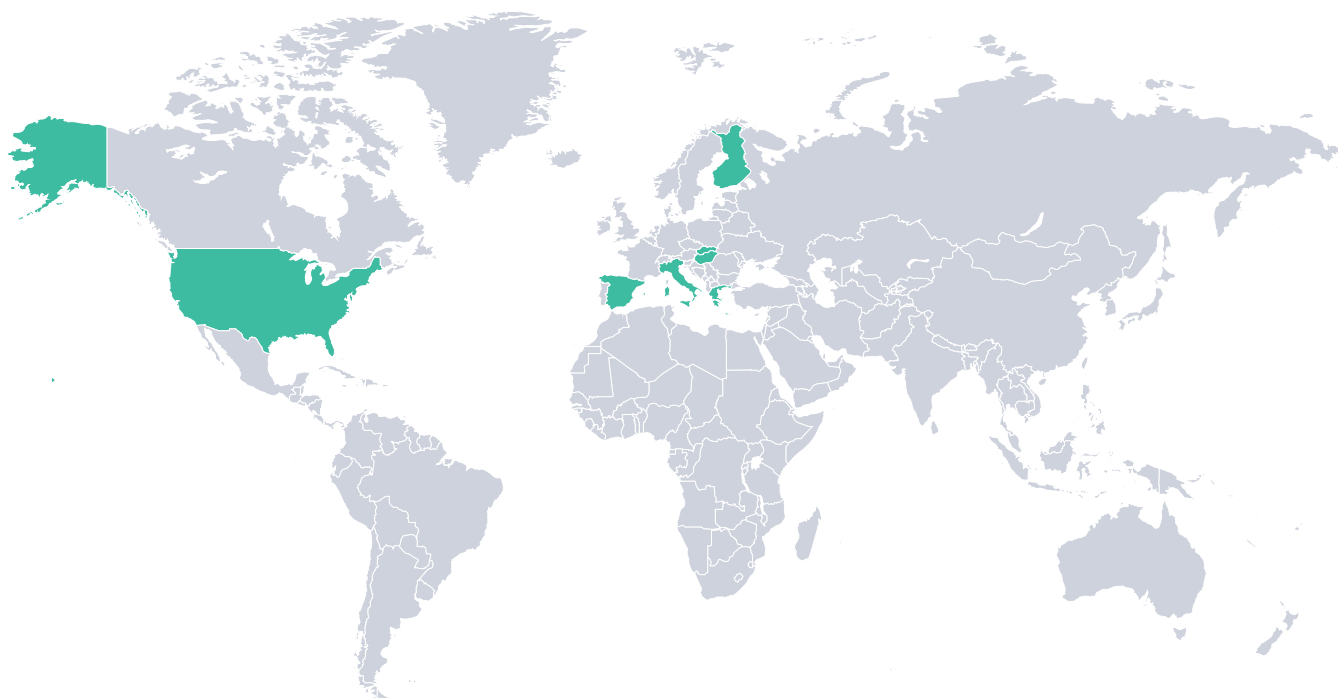
Researchers planned this study as a Phase 3b, open-label, randomized study.

- **Phase 3b studies** test approved products to provide additional information on different aspects of the condition or disease the study drug is approved for. In this study, the study doctors looked at the benefits of LCIG in patients compared to the current standard PD treatment.
- This study **randomized** patients, which means that patients were randomly (by chance) assigned to treatment groups.
- This study was also "**open-label**", which means that both the patients and the study doctors knew which treatment was given.

The main goal of the study was to find out whether treatment with LCIG improved dyskinesia in comparison to the current standard treatment in patients with advanced PD. The study doctors also looked for any side effects patients may have had after treatment with the study drugs. This summary only includes the results of this study, which may be different from the results from other studies for advanced PD.

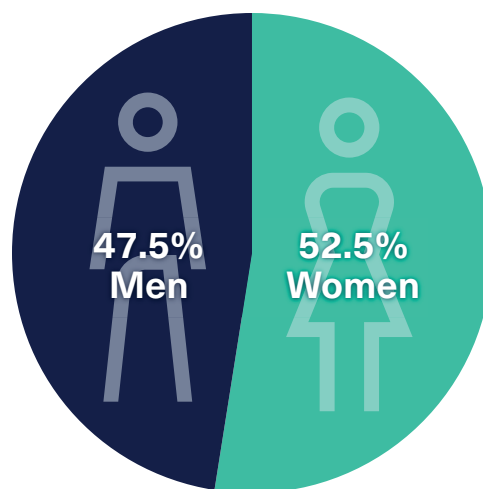
1.2 When and where was the study done?

This study took place from February 2017 to September 2019 in the following countries: Finland, Greece, Hungary, Italy, Slovakia, Spain, and the United States.



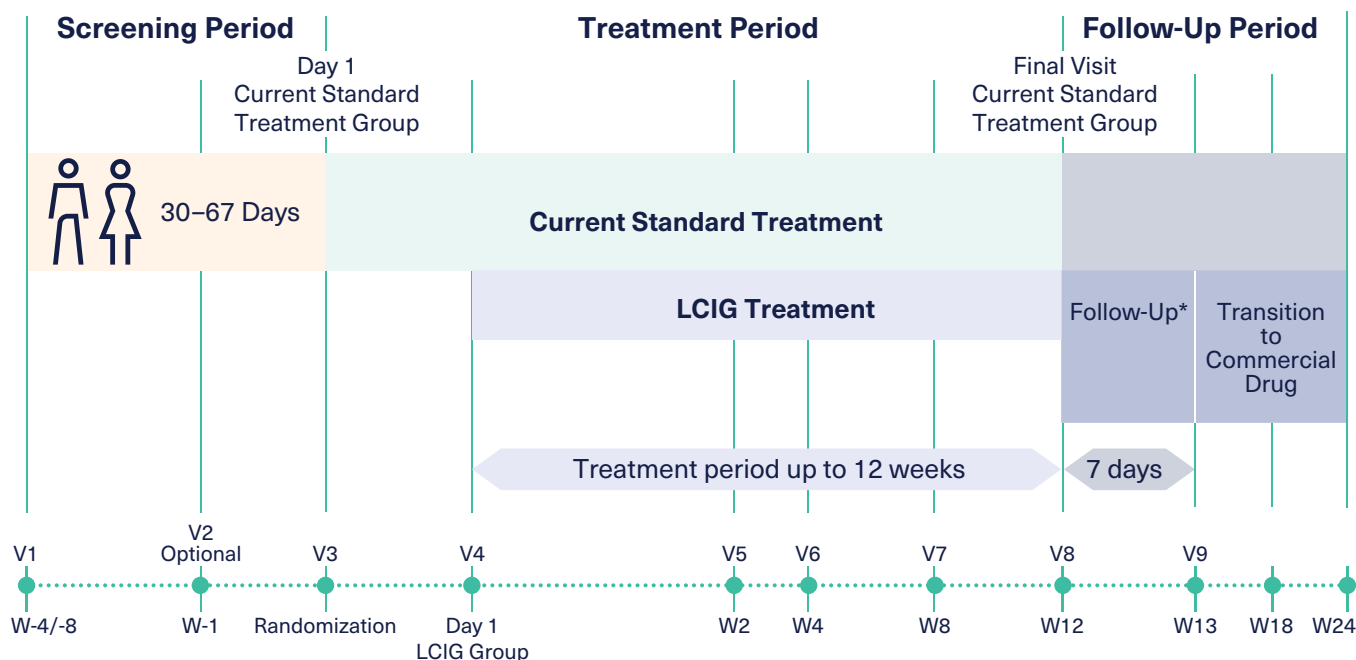
2. What patients were included in this study?

A total of 61 adult patients took part in the study; of these, 7 patients left the study, mostly due to withdrawal of consent. About the same number of men (47.5%) and women (52.5%) participated in the study. Patients ranged from 46 to 83 years of age, with a median age of 70. Study doctors selected only adults to participate in this study. Patients must have had idiopathic PD, which means the cause of their PD was unknown. Patients must have also been responding to treatment with levodopa before participating in the study. The majority of patients (65.0%) had PD for 10 years or more, and 93.4% of patients had been responding to levodopa for more than 5 years.



3. Which medicines were studied?

The medicine in this study was Levodopa-Carbidopa Intestinal Gel (LCIG). The diagram below shows how the study was organized.



*For patients who did not complete LCIG treatment or completed treatment and did not wish to transition to commercial drug

V (visit), W (week), LCIG (Levodopa-Carbidopa Intestinal Gel)

The study was divided into 3 parts: Screening Period, Treatment Period, and Follow-Up Period. Before the study started, the Screening Period took place to check if patients met the entry criteria so they could join the study. Once patients were screened, they were randomly (by chance) assigned to treatment groups (current standard treatment or LCIG treatment) with both patients and study doctors knowing which treatment they were assigned to. The total time of participation from Screening to Follow-Up was approximately 6 months.

In the Treatment Period, patients in the current standard treatment group continued taking their current PD medication as prescribed by their doctor. Patients in the LCIG group stopped taking their current Parkinson's medication and transitioned to treatment with LCIG. Patients in the LCIG treatment group underwent a procedure to insert a tube into their intestinal region. This way, LCIG was able to be continuously administered via a gel delivered by a portable pump to their intestine. The dose of LCIG was adjusted for each patient until the best response for each patient was achieved.

Patients who completed LCIG treatment for 12 weeks and wished to continue LCIG treatment went to visits with their study doctors to check their overall health and monitor any changes in their condition during the "Transition to Commercial Drug" period. Patients who received LCIG but did not complete the 12-week LCIG treatment or completed the study but chose not to transition to the commercial drug went to a final Follow-Up visit 1 week after their portable pump removal.

4. What were the side effects?

Side effects are unwanted medical events that happen during a study. They may or may not be caused by the treatment in the study, and they may or may not be related to the disease.

A side effect is serious if it leads to death, is life-threatening, puts a patient in the hospital, keeps a patient in the hospital for a long time, or causes a disability that lasts a long time.

Related side effects are side effects that were considered by the study doctor to be at least possibly related to the study treatment.

- About 3.3% of patients (2 patients) had serious side effects during the study. One of these patients had a serious side effect (syncope [fainting]) that was considered related to study treatment.
- About 3.3% of patients (2 patients) stopped treatment because of side effect(s) during the study. None of these side effects were considered related to study treatment.
- No patients died during the study.

The table below shows information about the related serious side effects patients had during the study, as well as related side effects patients had that led to the patient stopping the study drug, and related side effects leading to death.

Overall Study		
	Current Standard Therapy (N=33 patients)	LCIG (N=28 patients)
Number of patients with related serious side effects	0 (0.0% of patients)	1 (1.6% of patients)
Related serious side effects in 1 or more patients		
• Syncope (fainting)	–	1 (1.6% of patients)
Number of patients who stopped taking study drug because of related side effects	0 (0.0% of patients)	0 (0.0% of patients)
Number of related side effects leading to death	0 (0.0% of patients)	0 (0.0% of patients)

About 27.3% of patients (9 patients) who received current standard treatment and 64.3% of patients (18 patients) who received LCIG had side effects during the study. The total number of patients that had side effects considered possibly related to the study treatment was 3 patients (9.1% of patients) who received current standard treatment and 8 patients (28.6% of patients) who received LCIG.

The table below shows information about the common related side effects (in at least 2 or more patients) in this study. The most common related side effect was procedural pain (pain during placement of the pump).

Overall Study		
	Current Standard Therapy (N=33 patients)	LCIG (N=28 patients)
Number of patients with at least one related side effect	3 (9.1% of patients)	8 (28.6% of patients)
Procedural pain (pain during placement of the pump)	0 (0.0% of patients)	3 (10.7% of patients)
Vitamin B6 deficiency	1 (3.0% of patients)	1 (3.6% of patients)
Parkinson's disease (worsening of PD symptoms)	1 (3.0% of patients)	1 (3.6% of patients)

More side effects were seen in the LCIG treatment group than the current standard treatment group.

5. What were the overall results of the study?

This study found that treatment with LCIG significantly decreased dyskinesia compared to current standard treatment in patients with advanced idiopathic PD. The effect of the study drugs on dyskinesia was measured using a specific rating scale known as the Unified Dyskinesia Rating Scale (UDysRS) Total Score, which measured changes in involuntary movements from before study treatment through Week 12. The beneficial effects of LCIG were seen as early as 2 weeks after the start of treatment, and continued throughout the rest of the Treatment Period.

More patients who received treatment with LCIG experienced side effects compared to patients who received current standard treatment. Side effects in this patient population were similar to side effects seen with the medical procedures performed in other previous LCIG studies and amongst patients with PD.

6. How has the study helped patients and researchers?

This study found that patients treated with LCIG had improved symptoms of dyskinesia compared to patients treated with current standard treatment. This study also found that LCIG is generally well tolerated. Results from this study may be used in other studies to learn whether patients are helped by LCIG.

This summary only shows the results of this study, which may be different from the results of other similar studies. Patients should consult their physicians and/or study doctors with further questions about their individual care and should not make changes in their treatment based on the results of a single study.

7. Are there any plans for future studies?

There is a possibility for future studies that include LCIG.

8. Who sponsored this study?

This study was sponsored by AbbVie Inc. This summary was reviewed for readability by a patient advocacy group.

9. Where can I find out more information about this study?

Title of Study	An Open-label, Randomized 12 Week Study Comparing Efficacy of Levodopa-Carbidopa Intestinal Gel/Carbidopa-Levodopa Enteral Suspension and Optimized Medical Treatment on Dyskinesia in Subjects with Advanced Parkinson's Disease
Protocol Number	M15-535
Clinicaltrials.gov	NCT02799381 https://clinicaltrials.gov/ct2/show/NCT02799381
EudraCT	2016-001403-23 https://www.clinicaltrialsregister.eu/ctr-search/search?query=2016-001403-23
AbbVie.com	https://www.abbvie.com/our-science/clinical-trials/clinical-trials-data-and-information-sharing/results-summaries-for-study-participants.html
Publication Citation	Not available
Study Sponsor	AbbVie Inc. Phone: +1 800-633-9110 Email: abbvieclinicaltrials@abbvie.com

Thank You

AbbVie wants to thank all the participants for their time and effort that went into making this study possible.

Clinical study participants help advance science!

