Investigating the effectiveness and safety of ND0612, an investigational medicine for patients with advanced Parkinson’s Disease
WHAT IS ND0612?
ND0612

ND0612 is a novel liquid formulation of levodopa/carbidopa (LD/CD) aimed to reduce motor complications in patients with advanced Parkinson's Disease.

ND0612 is designed in low-dose (ND0612L) and high-dose (ND0612H), administered subcutaneously (just under the skin) through a mini-pump, enabling 24-hour continuous LD/CD administration.
In a phase II placebo controlled study, ND0612L was shown to maintain steady, therapeutic levodopa plasma concentrations that were associated with major changes in clinical parameters such as "OFF time" reduction when added to optimal oral standard of care.\(^1\)

\(^1\) N. Giladi, Y. Caraco, T. Gurevich et al, 19th International Congress of Parkinson’s Disease and Movement Disorders. Late-Breaking Abstracts, Stable levodopa plasma levels with ND0612 (levodopa/carbidopa) for subcutaneous infusion in Parkinson’s Disease (PD) patients with motor fluctuations.
In a phase IIa study, **ND0612H** was shown to reach higher levodopa steady plasma levels, indicating that it may provide an effective alternative to current treatments requiring surgery, such as deep brain stimulation and LD/CD Intestinal Gel.


New medication limited by Federal law to investigational use
YOU MAY BE ELIGIBLE TO PARTICIPATE IN THESE STUDIES IF YOU ARE:

30 to 80 years old

Taking at least 4 doses/day of levodopa

Experiencing a minimum of 2-2.5 hours of “OFF” time per day with predictable early morning “OFF” periods

ND0612 CLINICAL STUDIES

TREATMENT DURATION: 4-52 WEEKS
To learn more about the studies and get involved please visit: WWW.NEURODERM.COM
Additional sites will be added in the near future.

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“OFF” PERIODS
SHOULDN’T INTERFERE WITH YOUR DAILY LIVING
New medication limited by Federal law to investigational use
IF YOU OR A LOVED ONE ARE BEING TREATED FOR ADVANCED PARKINSON’S DISEASE, CONSIDER ND0612 CLINICAL STUDIES

Most medications for Parkinson’s Disease begin to lose effectiveness after several years of use. Without access to an effective medication, patients with Parkinson’s Disease begin to experience more “OFF” periods, which have a significant impact on daily life. Treatments that reduce “OFF time” are needed.

Pharmaceutical companies use research studies like the ones for which we are enrolling patients to learn more about investigational medications before they are made available to the public. The results of these studies will provide more information about the investigational medication’s effect on Parkinson’s Disease. By taking part in these studies, you may contribute to the development of medications for Parkinson’s Disease patients in the future.
ND0612 CLINICAL STUDIES

ND0612 clinical studies are evaluating an investigational Parkinson’s Disease treatment that uses a pump system to deliver an infusion of the investigational medication, a solution of levodopa and carbidopa, through a small needle that is inserted beneath the skin.

By using an infusion to deliver the investigational medication continuously, it could offer more effective control of “OFF” periods than oral medications.

Researchers designed these clinical studies to protect the rights and welfare of those participating. Independent review boards reviewed and approved these research protocols and related materials (e.g. explanatory documents and informed consents), and will monitor the progress of the studies.

Currently, only patients who participate in research studies like these can receive the investigational medication. It is not approved by regulatory agencies for the treatment of Parkinson’s Disease. As with any medical research study, the investigational medication is not guaranteed to help your Parkinson’s Disease.
WHAT ARE THE RISKS RELATED TO THESE STUDIES?

• Though the investigational medication has been studied before, and was found to be tolerable, it is possible you could experience side effects. Because research studies can affect the health and safety of participants, you will be closely monitored during the study if you participate in these studies.

• To date, 138 people (healthy volunteers and patients with Parkinson’s Disease) were treated with continuous subcutaneous infusion of the study drug.

  - The most commonly reported adverse effects were local skin infusion site reactions. Nearly all subjects reported subcutaneous nodules at the infusion sites, which were generally not associated with pain. The nodules resolved spontaneously within an average of 2-3 months. Approximately 50% of patients reported mild and transient pain, erythema (superficial reddening of the skin) and edema (a condition characterized by an excess of watery fluid collecting in the cavities), at the infusion sites, which resolved spontaneously.

  - Other common adverse events included local hemorrhage (bruising) at the infusion sites and headache.

  - The study drug contains levodopa and carbidopa which are known to be associated with adverse events, the most common being dyskinesia (abnormal involuntary movements), nausea, vomiting, dizziness, low blood pressure upon rising, headache, sleeplessness, dry mouth, anxiety and constipation.

  - Serious side effects that are known to be associated with LD/CD medications are hallucinations and delusions, unexpected falling asleep (e.g. during driving), unusual urges and high fever and confusion related to medication withdrawal.

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