CLINICAL STUDY RESULTS

A Study to Identify How a Single Oral Dose of IPN60170 (Mesdopetam) Is Taken Up, Broken Down and Removed from the Body of Healthy Adult Men

IPN60170 was absorbed quickly in the body after being given by mouth as a solution. IPN60170 was removed from the body, mainly through urine.

The results shown in this summary represent one clinical study. Other clinical studies may produce different results.

This lay summary was created by Ipsen with the assistance of a third-party writing service provider.

What was the study about?

IPN60170 is a drug that is under development for the treatment of a condition called levodopa-induced dyskinesia (LID) in people with Parkinson's disease (PD).

PD occurs due to a lack of dopamine in the brain, causing strong bodily shaking, stiffness, and problems with balance, coordination, and walking. Levodopa is a drug used to treat people with PD. However, levodopa causes side effects including involuntary and erratic movements of the face, arms, legs, or trunk. These symptoms are called LID.

This study was conducted in healthy men, so it did not test whether IPN60170 improved participants' health. Researchers wanted to know how IPN60170 enters, travels through the blood, and how it is broken down and removed from the body.

To track how the drug moves through the body, researchers used a "radiolabelled" form of IPN60170. A radiolabel is a radioactive particle attached to a study drug that lets researchers measure the amount of study drug in the body. Adding a low level of radioactive particle to IPN60170 does not change how the drug works. Researchers also wanted to see how IPN60170 was broken down or changed by the body. This was done by measuring the amount of drug "metabolites" of IPN60170. Metabolites are the chemicals formed as a drug is broken down by the body.

The findings of this study will help researchers to understand if IPN60170 can be further tested in people with PD.

The main aim of the study was to identify how IPN60170 is absorbed into the blood, broken down and removed from the bodies of healthy men.

The study took place between October 2022 and December 2022 at 1 trial site in the Netherlands.

Who took part in this study?

7 PARTICIPANTS	All MEN	35 YEARS AVERAGE AGE

To take part in the study, participants had to be:

- healthy males between 18 and 55 years of age and within a certain weight range, and
- able to swallow an oral solution form of IPN60170.

Participants could not take part in the study if they had:

- certain medical conditions, or were taking certain medications, that could affect the study results, and
- any disease that affects the body's process of breaking down and removing medication from the body.

All 7 participants who started the study finished the study as planned.

What treatments were used in this study?

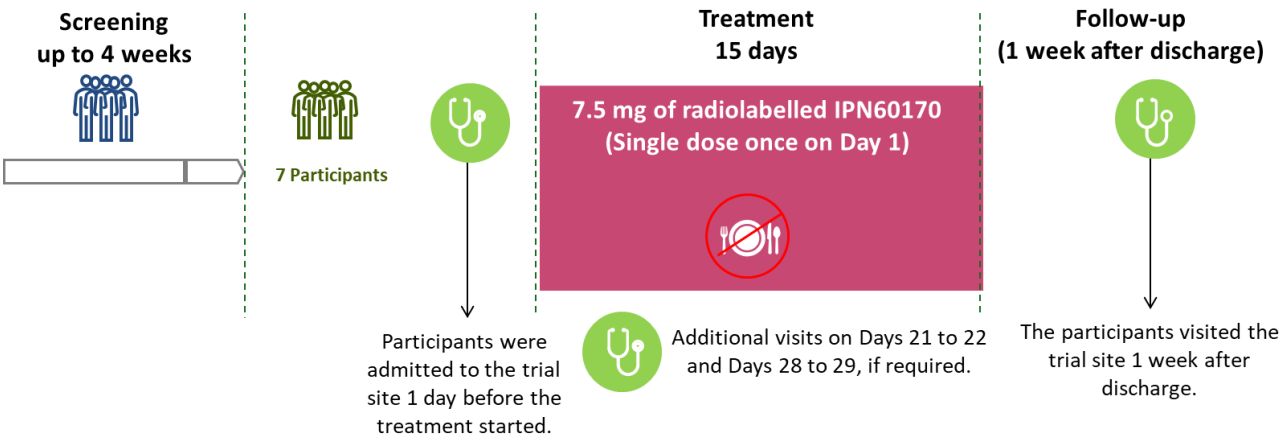
Study Treatment

A single total dose of 7.5 milligrams (mg) of radiolabelled IPN60170 was given by mouth as a solution to drink on Day 1 of the study.

This study had 3 parts:
Screening: The study doctor checked if participants could take part in this study within 4 weeks before starting the study treatment.

Treatment: Participants were admitted to the trial site 1 day before the start of treatment. Before taking study treatment, the participants did not eat or drink anything except water for at least 10 hours. All 7 participants received the study treatment in the morning. The participants did not eat or drink anything except water until 4 hours after taking the study treatment. Participants stayed at the trial site for up to 15 days. Each day at the trial site the trial doctors took blood, urine, and stool samples.
By Day 15, if at least 90% of the radiolabelled IPN60170 had been removed from their bodies through urine and stools, participants were discharged. Otherwise, they had to return to the trial site for up to 2 additional 24-hour visits on Days 21 to 22 and Days 28 to 29.
This study was "open label". This means that the researchers and the participants knew the treatment that was given to the participants.

Follow-up: The participants visited the trial site 1 week after discharge for a final health check.



What did researchers find out in the study?

- Radiolabelled IPN60170 were absorbed quickly into the blood.
- Almost the entire radiolabelled IPN60170 was removed from the body through urine and stools within 1 week of taking it.

How was radiolabelled IPN60170 processed in participants' blood and plasma* after receiving it?

**Plasma is the liquid part that makes up most of the blood.*

The study found that:

- The radiolabelled IPN60170 was absorbed quickly into blood and plasma. The time to reach the highest concentration of radioactivity was 1 hour in both blood and plasma.
- The radiolabelled IPN60170 was completely removed from blood and plasma within 24 to 48 hours after dosing.

How much radiolabelled IPN60170 was found in the participants' urine and stools?

The study found that 99% of radiolabelled IPN60170 that participants took was found in their urine, and less than 1% was found in their stools. Most of the drug was eliminated from the participants' bodies in the first 7 days after taking the drug.

How was IPN60170 broken down in participants?

The study found that there were 3 main breakdown products (metabolites) of IPN60170 in participants' bodies (called "M1", "M7" and "M6").

- IPN60170 was a main component found in the participants' blood, with an average of about 54%. Metabolites M7, M6 and M1 made up about 13%, 12% and 10%, in the participants' blood, respectively.
- An average of 33% of the drug was removed through urine in the form of IPN60170. Rest was removed as its metabolites—28% as M7, 20% as M1, and 15% as M6.

How did the treatment make participants feel?

During the study, participants were asked to report any 'adverse events', that is, if they felt unwell, experienced any kind of medical event, or noticed anything different about their bodies. Researchers recorded all adverse events reported by participants, whatever the cause. For example, some participants caught COVID-19 and this was reported as an adverse event, although it was not related to the study treatment.

If the study doctor thinks an adverse event may be related to the study treatment, it is called a 'side effect'. A side effect is considered 'serious' when it is life-threatening, causes lasting problems, or leads to hospitalisation.

- Adverse events that are life-threatening, cause lasting problems or require an individual to go to the hospital are considered serious.
- No participant died or experienced a serious side effect during this study.

None of the participants experienced a side effect or stopped taking part in the study because of a side effect.

More information

For more information about current treatments available, please speak to your healthcare provider. If you have any questions about this study, please contact the sponsor, Ipsen at:

clinical.trials@ipsen.com

Future research

There is no future research planned on this topic.

Study identification and other information

FULL STUDY TITLE: A Phase 1, Open-label, Single-dose, Single-Centre, Mass Balance Study Following a Single 7.5 mg Oral Dose of IPN60170 Containing 105 µCi of [14C]-IPN60170 in Healthy Adult Male Participants.

STUDY NUMBERS: Europe: Not available| United States: Not available |

PROTOCOL: CLIN-60170-451

OTHER INFORMATION: Phase I studies can take several months to years to complete and look at how safe a potential new treatment is.

We thank all the volunteers who took part in this study. Without their support, advances in treatments for medical conditions would not be possible.

We would also like to thank the people who took the time to review this document to make it easier for a general audience to read.