CLINICAL STUDY RESULTS

A Study to Compare the Levels of IPN60170 (Mesdopetam) in the Blood of Healthy Japanese, Chinese and Non-Asian Volunteers

This study showed that levels of different doses of IPN60170 (Mesdopetam) in the blood of healthy Japanese and Chinese participants were similar compared to healthy non-Asian participants.

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

This lay summary has been produced by Ipsen with the assistance of a third party writing service provider.

What was the study about?

IPN60170 was developed to treat a condition called levodopa-induced dyskinesia (LID) in patients with Parkinson's disease (PD).

PD happens due to a lack of dopamine in the brain, causing strong body shaking, stiffness, and problems with balance, coordination, and walking. Levodopa is a drug used to treat PD patients. However, it causes side effects like involuntary and uneven (erratic) movements of the face, arms, legs, or trunk called LID. IPN60170 is a drug that is being developed for the treatment of LID.

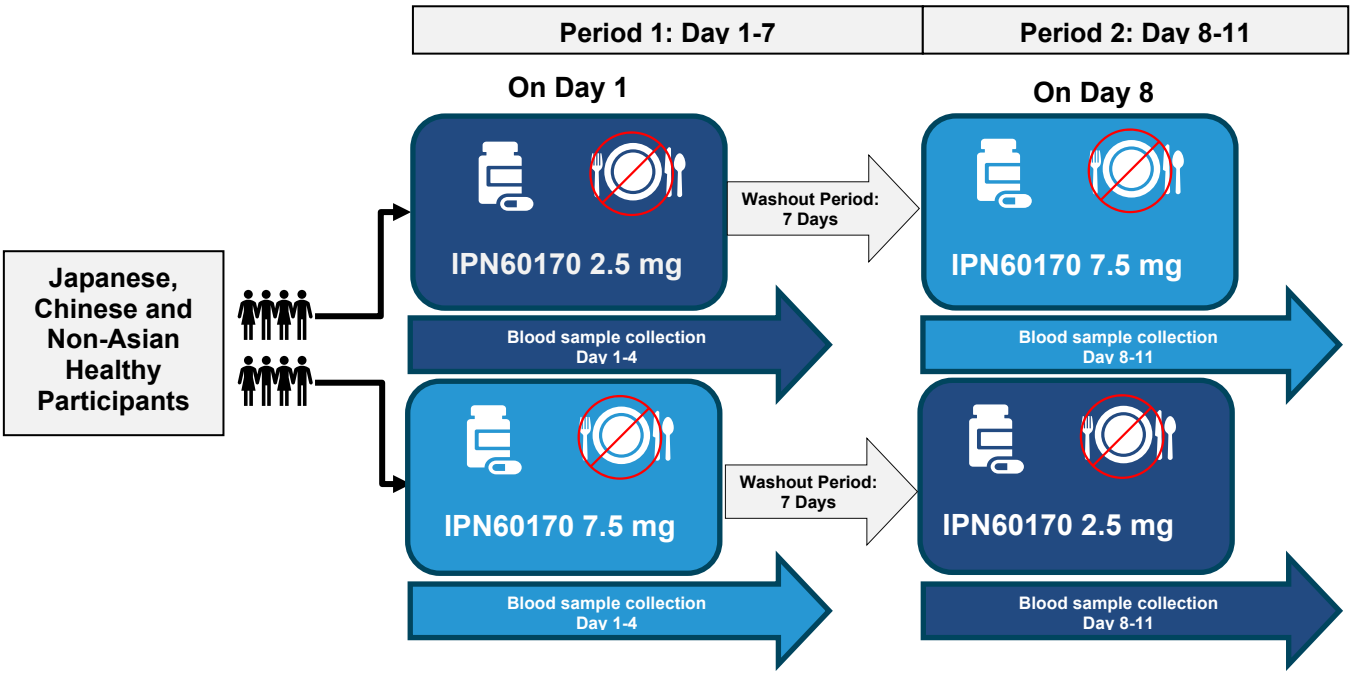
Researchers wanted to know how IPN60170 enters and travels through blood, how it is broken down and removed in Japanese and Chinese healthy participants' bodies, so that they could be included in future studies of IPN60170. In this study, researchers wanted to find out and compare the levels of IPN60170 in the blood of healthy Japanese or Chinese and non--Asian participants. The findings of this study will help researchers understand if IPN60170 can be further tested in people with PD.

> The aim of this study was to compare the levels of different doses of IPN60170 in the blood of healthy Japanese and Chinese participants compared to healthy non-Asian participants.

This study took place between May 2022 and January 2023 at one study site in the United States of America.

This was an "open label" study, which means that both researchers and participants knew participants were receiving IPN60170.

Study Design:



The participants' health was monitored throughout the study. Blood samples were collected at defined timepoints over 4 days after each IPN60170 administration to measure the level of IPN60170.

Who took part in this study?

Three groups of a total of 43 healthy participants took part. One group of 16 healthy Japanese participants, one group of 13 healthy Chinese participants and one group of 14 healthy non--Asian participants. The groups were matched with respect to sex, age, and weight.

43
16 Japanese
13 Chinese
14 Non-Asian

All
MEN

41 YEARS
AVERAGE AGE

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

- be healthy Japanese, Chinese or non--Asian,
- be adults aged between 18 and 55 years old weighing 45 kilograms (100 pounds) or more,
- for Japanese participants, be born in Japan, with Japanese parents and grandparents,
- for Chinese participants, be born in China, with Chinese parents and grandparents,
- had normal functioning CYP1A2 and CYP2D6 liver proteins.

Participants were not eligible to take part in the study if they had:

- a history of certain medical conditions and hospitalization,
- any disease condition that interferes with the way the body absorbs, distributes, and gets rid of drugs,
- a major operation held within 6 months.

What treatments were used?

Each participant received 2 single doses of 2.5 mg and 7.5 mg of IPN60170 by mouth in the form of capsules. Participants took each dose of IPN60170 on an empty stomach, after not eating for at least 10 hours. There was a gap of 7 days between the two doses.

There were two treatment periods during the study: Period 1 and Period 2. Participants were 'randomised' (assigned randomly using a computer program) to receive either the 2.5 mg or 7.5 mg dose in Period 1 and the second dose in Period 2. During Period 2, the participants took a different dose from the Period 1.

What were the levels of IPN60170 in the blood of healthy Japanese and Chinese participants compared to healthy non-Asian participants?

To answer this question, researchers collected blood samples from the participants at certain timepoints over 4 days after they took IPN60170, to measure the levels of IPN60170 in the blood over time.

The study showed that the highest level of IPN60170 in the blood was similar. The total amount of IPN60170 in the blood was slightly lower in Japanese participants compared to non-Asian participants.

The highest level and the total amount of IPN60170 in the blood were similar in Chinese and non-Asian participants.

The study showed that the levels of IPN60170 in the blood of healthy Japanese and Chinese participants were similar to healthy non-Asian participants.

How did the treatment make participants feel?

During clinical studies, participants are asked to report if they feel unwell, experience any kind of medical event, or notice anything different about their bodies. These are called 'adverse events.' Researchers record *all* adverse events reported by participants, whatever the cause.

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.

No participant died or experienced a serious side effect in this study. One Chinese participant experienced mild dizziness, which was thought to be caused by IPN60170 2.5 mg.

- Side effects that are life-threatening, cause lasting problems or require an individual to go to the *hospital* are considered s*erious*.
- No participant died or experienced a serious side effect.

IPN60170 was generally well tolerated by participants. No participant 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, Randomised, Single-centre, Open-Label, Cross-Over, Single-Dose Study to Assess the Pharmacokinetics, Safety, and Tolerability Following Administration of IPN60170 in Healthy Japanese, Chinese and Non-Asian Participants.

PROTOCOL: CLIN-60170-452.

OTHER INFORMATION: Phase I studies can take several months 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.