

Summary of Results

Safety

Unwanted effects, also called adverse reactions, are medical problems that happen during a study. They are described here because the study doctor believes the unwanted effect was related to the medicine studied in the study. Unwanted effects may be mild to serious. Serious unwanted effects are those that can result in death, hospitalisation or could extend the time a participant has to spend in the hospital.

In this study there were no serious unwanted effects reported. There were in total 9 unwanted effects thought to be related to the study medication – all were of mild severity.

Scintigraphy

The study looked at how the two tablets (CP-012A and CP-012B) travelled through the gut and where and when they dissolve using an imaging technique called scintigraphy. Most of the time the tablets dissolved within the stomach or small intestine. Overall, both treatments behaved similarly, with Treatment B taking a bit longer to start and finish releasing drug, as intended.

Pharmacokinetics

The study also compared how the body absorbed levodopa and carbidopa from the delayed release Treatments (CP-012A and CP-012B) compared to a standard immediate release Treatment C (Sinemet PLUS) by measuring levels of drug in the blood (pharmacokinetics). Blood tests taken at different time intervals after dosing showed that the study medicine entered the bloodstream after dosing, reached a highest level, and was then gradually removed from the body.

Conclusion

This study showed that CP-012 was well tolerated, that there were no serious unwanted effects and that there was no new safety concerns found. Scintigraphic imaging showed that it took some time before the CP-012 tablets started to dissolve within the stomach or gut. Blood levels demonstrated that Sinemet PLUS released the medicine quickly, so drug levels in the blood rose fast, but they did not remain in the blood for as long. With CP-012, the medicine took longer to reach its highest level in the bloodstream and remained in the blood for a longer time.