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Assessing the Efficacy of Peko-D Forte as Add-on Therapy for Parkinson's Disease: A Proof of Concept, Double-Blind, Placebo-Controlled Study

Évaluation de l'efficacité de Peko-D Forte en tant que traitement adjuvant de la maladie de Parkinson : une étude de preuve de concept, en double aveugle et contrôlée par placebo

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ABSTRACT

BACKGROUND: *Hypoestes rosea*, an endemic shrub in Nigeria and Cameroon with documented anti-inflammatory properties, has been shown to modify disease progression in transgenic mouse models with Parkinson's Disease PD. We investigated the efficacy and side effect profile of *Hypoestes rosea* (Peko-D forte) in improving motor performance of PD patients

METHODS: This double-blind, randomized, placebo-controlled, proof-of-concept (phase I) study involved 19 patients with mild to moderate PD. Routine dopaminergic therapy was maintained. Following randomization, half of the patients received 4 capsules each of 350 mg Peko-D forte tablets, and the other half, 4 capsules of matching placebo (USP-grade starch) for 8 weeks. After a wash-out period of 4 weeks, patients were switched over (cross-over design). The effects of the medication on motor activity were analyzed using the Unified Parkinson's Disease Rating Scale (UPDRS).

RESULTS: Overall, 14 patients completed the study, comprising 93% males with a mean age of 72 (13.2) years. Their median (IQR) UPDRS score at baseline of 18 (13-20) improved significantly with both Peko-D forte 12 (6 – 16) and placebo 12.5 (9- 15) ($p < 0.001$). Compared to baseline, Peko-D forte improved bradykinesia, rest tremor amplitude and frequency, and rigidity. There was no significant difference between the median UPDRS score with the use of Peko-D forte compared to placebo. The test drug had 93% tolerability with a good side effect profile

CONCLUSION: Peko-D forte improved motor functions in PD, and it is safe and tolerable. Its efficacy is unclear due to the lack of significant difference between the test drug and placebo. Larger studies will be needed to confirm its efficacy. Clinical Trials.org (NCT04858074). **WAJM 2024; 42 (1): 61-66**

KEYWORDS: Parkinson's Disease, PD add-on therapy, PD Pharmacotherapy, Peko-D Forte, Proof of Concept Study, Placebo-controlled study, Nigeria, West Africans

RÉSUMÉ

CONTEXTE: *Hypoestes rosea*, un arbuste endémique du Nigéria et du Cameroun ayant des propriétés anti-inflammatoires documentées, a montré une capacité à modifier la progression de la maladie dans des modèles murins transgéniques de la maladie de Parkinson (PD). Nous avons étudié l'efficacité et le profil des effets secondaires de *Hypoestes rosea* (Peko-D forte) pour améliorer les performances motrices des patients atteints de PD.

MÉTHODES: Cette étude de preuve de concept (phase I), en double aveugle, randomisée et contrôlée par placebo, a impliqué 19 patients atteints de PD légère à modérée. La thérapie dopaminergique habituelle a été maintenue. Après randomisation, la moitié des patients ont reçu 4 capsules de comprimés de Peko-D forte (350 mg chacun), tandis que l'autre moitié a reçu 4 capsules de placebo correspondant (amidon USP-grade) pendant 8 semaines. Après une période de lavage de 4 semaines, les patients ont été interchangés (schéma en croisement). Les effets du médicament sur l'activité motrice ont été analysés à l'aide de l'Échelle Unifiée d'Évaluation de la Maladie de Parkinson (UPDRS).

RÉSULTATS: Au total, 14 patients ont terminé l'étude, dont 93 % d'hommes avec un âge moyen de 72 (13,2) ans. Leur score UPDRS médian (IQR) au départ de 18 (13-20) s'est significativement amélioré avec Peko-D forte 12 (6 – 16) et avec le placebo 12,5 (9-15) ($p < 0,001$). Comparé à la ligne de base, Peko-D forte a amélioré la bradykinésie, l'amplitude et la fréquence des tremblements au repos, ainsi que la rigidité. Aucune différence significative n'a été observée entre le score médian UPDRS obtenu avec Peko-D forte et celui obtenu avec le placebo. Le médicament a été bien toléré à 93 % avec un bon profil d'effets secondaires.

CONCLUSION: Peko-D forte a amélioré les fonctions motrices des patients atteints de PD, et il est sûr et bien toléré. Son efficacité reste incertaine en raison de l'absence de différence significative entre le médicament testé et le placebo. Des études de plus grande envergure seront nécessaires pour confirmer son efficacité. Clinical Trials.org (NCT04858074). **WAJM 2024; 42 (1): 61-66**

MOTS-CLÉS: Maladie de Parkinson, Thérapie adjuvante de la PD, Pharmacothérapie de la PD, Peko-D Forte, Étude de preuve de concept, Étude contrôlée par placebo, Nigéria, Africains de l'Ouest.

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