

ABSTRACT

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Protocol proposal: N-of-1 clinical trials in equine osteoarthritis

Mário Domingues de Castro¹, Leoni Villano Bonamin¹

¹ Graduate Program in Environmental and Experimental Pathology, Paulista University UNIP, São Paulo, Brazil

* marioetec@gmail.com – <https://orcid.org/0009-0003-4221-9107>

Osteoarthritis (OA) is a chronic degenerative disease characterized by pain and stiffness. At this stage, joint homeostasis is broken, leading to degeneration of cartilage and adjacent tissues. The focus of this research is to prove that the use of the homeopathic complex Drenareuma WP® (Curitiba, Brazil), composed of *Bryonia alba* 4cH, *Mezereum* 6cH, *Ranunculus bulbosus* 5cH, *Rhus Toxicodendron* 5cH, *Ruta graveolens* 5cH and excipients, modulates the bone/articulation restoration of its homeostasis and organization of joint morphological structures, with the animal's return to sport and service [1]. Six horses will be selected from the veterinary polyclinic of UNIP, São José dos Campos, Brazil, and subjected to a series of N of 1, crossover, and multiple-trial trials [2]. N-of-1 trials provide rigorous evidence of intervention effects for individuals, enabling the improvement of patient-centered, evidence-based care [3]. Each patient's treatment (verum) or placebo period will be organized into two series of alternating 90-day blocks (or cycles). On days 0 and 90 (D0 and D90) of each block, the most affected joint will be carefully examined, lameness will be scored [4], and local temperature will be measured using a thermal camera. They will undergo diagnostic imaging techniques in orthogonal radiographic projections (lateromedial, flexed lateromedial, dorsopalmar, dorsolateral-palmaromedial oblique 45° and dorsomedial-palmarolateral oblique 45° projections (5, 6), longitudinal and transversal sections of ultrasound images. The thickness and spaces of the analyzed structures will be scored from an adaptation of a standard knee scale [7]. The entire data set will be evaluated using Bayesian statistics, comparing D0 to D90 in each period and the total cycle. This protocol will be submitted to the Animal Ethics Committee for approval. N-of-1 offers important new investigative possibilities in homeopathy, allowing for individualized and efficacy-based investigation of homeopathic interventions compared to placebo in individuals [3].

Keywords: Homeopathic complex, Equine osteoarthritis, N-of-1 trials

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