

Les essais cliniques: présentation de Myriam Raj, FARA, lors du webinaire du 19 novembre 2023

Développeur de l'essai	Lexon Therapeutics	Design Therapeutics	Larimar Therapeutics	Children's Hospital of Philadelphia (CHOP)	Rasta Pharmaceuticals	PTC Therapeutics	
Composé	LX2006 (AAV9, 10Mg XN)	DT-295	CTL1601	NAD ⁺ et exercice	Oxamveloxane (RTA-408)	Vatiquinone (PTC-743)	
Principe	Thérapie génique par virus adéno-associé (AAV) pour la cardiomyopathie, conçue pour porter le gène de la titaxine humaine aux cellules cardiaques. Pourrait atteindre le cœur, le muscle squelettique et d'autres tissus périphériques.	Petites molécules, les "Gène-TAC" qui ciblent l'expansion GAA et, en construisant "un pont", réactivent le gène de la titaxine.	Protéine de fusion. Apporte la titaxine humaine directement aux tissus par injection sous-cutanée.	NAD ⁺ est converti en NADH dans la cellule. Très important au sein de la mitochondrie pour produire de l'énergie. L'exercice augmente la masse musculaire, la capacité pulmonaire et cardiaque et améliore la fonction mitochondriale.	Active le NAD ⁺ (antioxydant cellulaire). Augmente l'expression des gènes « antioxydants ». Protège les cellules des dégâts consécutifs.	Améliore l'équilibre mitochondrial et cellulaire en ciblant la 15-lipoxygénase, l'enzyme clé de régulation de la ferroptose.	
Âge des patients	Pour adultes présentant une cardiomyopathie	18 – 55 ans	Adultes de plus de 18 ans	18 – 40 ans	MOE: 18 – 40 ans	MOE/FA: Enfants de plus de 7 ans et adultes	Entre 2 et 5 enfants de moins de 7 ans
Durée du traitement	52 semaines - administré en 1 seule fois par voie intraveineuse	8 semaines	4 semaines	3 semaines	Toujours en cours	18 mois	72 semaines
État de développement	Phase 1/2 Deux groupes faible dose et haute dose (5 patients dans chaque groupe). Pas de placebo. Deux centres ouverts aux USA.	Phase 1: doses croissantes multiples (MAC) pour évaluer la sécurité, la tolérabilité, la pharmacocinétique et la pharmacodynamique de 3 doses hebdomadaires chez des patients adultes.	Phase 2 - pour déterminer la dose et étudier la distribution de la titaxine externe et la tolérabilité.	Recrutement (seulement aux USA, actuellement)	Attente d'approbation de la FDA (Agence américaine médicament). Soumission d'une demande d'autorisation de mise sur le marché à l'EMA (Europe) fin 2022.	Phase 2/3 en cours, pour évaluer l'efficacité et la sécurité.	Recrutement. Les enfants prennent la molécule active (pas de placebo). Un seul centre clinique aux USA, mais ils acceptent des enfants étrangers si les parents sont capables de comprendre le consentement éclairé et le signer.
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