

Project

The World Health Organisation (WHO) has included low back pain in its list of twelve priority diseases. Notably, Degenerative disc disease (DDD) presents a large, unmet medical need which results in a disabling loss of mechanical function. Today, no efficient therapy is available. Chronic cases often receive surgery, which may lead to biomechanical problems and accelerated regeneration of adjacent segments.

Our consortium partners have developed and studied stemcell-based, regenerative therapies with encouraging results in phase 1 and 2a trials. Patients exhibited rapid and progressive improvement of functional and pain indexes by 50% within 6 months and by 65% to 78% after 1 year with no side effects. In addition, MRI T2 relaxation measurements demonstrated a significant improvement.

To develop the world's first rigorously proven, effective treatment of DDD, RESPINE aims to assess, via a multicentre, randomized, controlled, phase 2b clinical trial including 112 patients with DDD, the efficacy of an allogeneic intervertebral mesenchymal stem cell (MSC)-based therapy.



This innovative therapy aims to rapidly (within 3 months) and sustainably (at least 24 months) reduce pain and disability.

In addition, the consortium aims to provide new knowledge on immune response & safety associated with allogeneic BM-MSC intradiscal injection. This simple procedure would be cost-effective, minimally invasive, and standardised.

The transfer to the clinic will be prepared at a cost below 10k€ thanks to the strategy of production of allogenic cells, automation & EU standardisation. At the end of the EUROSPINE trial, we aim to propose a broadly available and clinically applicable treatment for DDD, marketed by European SMEs.



<u>RESPINE is a project funded by the European Union's Horizon 2020 research and innovation</u> <u>program under grant agreement no 732163.</u>

UNIVERSITY HOSPITAL OF MONTPELLIER

191 av du Doyen Giraud 34295 MONTPELLIER cedex 5